Draft Methods Research Report

Developing and Assessing Contextual Frameworks for Research on the Implementation of Complex System Interventions

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None of the investigators has any affiliations or financial involvement that conflicts with the material presented in this report.

Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To improve the scientific rigor of these evidence reports, AHRQ supports empiric research by the EPCs to help understand or improve complex methodological issues in systematic reviews. These methods research projects are intended to contribute to the research base in and be used to improve the science of systematic reviews. They are not intended to be guidance to the EPC program, although may be considered by EPCs along with other scientific research when determining EPC program methods guidance.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality. The reports undergo peer review prior to their release as a final report.

We welcome comments on this Methods Research Project. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Developing and Assessing Contextual Frameworks for Research on the Implementation of Complex System Interventions

Structured Abstract

Objectives: This report presents the adaption of the Consolidated Framework for Implementation Research (CFIR)[1] to three complex system interventions involving process redesign, Patient-Centered Medical Homes (PCMH), and Care Transitions. The purpose of the adapted frameworks—the Contextual Framework for Process Redesign (CF-PR), Contextual Framework for Patient-Centered Medical Homes (CF-PCMH), and Contextual Framework for Care Transitions (CF-CT)—is to guide research on *how, why,* and *where* these interventions succeed or fail to achieve intended outcomes.

Data Sources. MEDLINE. Additional studies were identified through the gray literature and technical experts.

Methods. The adaptation was informed by the findings from a scan of selected process redesign, PCMH, and Care Transitions literature, which included articles in MEDLINE, the published and gray literature, and recommendations of content experts at the Agency for Healthcare Research and Quality (AHRQ). A Technical Expert Panel (TEP) for each topic reviewed the draft of the contextual frameworks and provided input on the structure and content through a series of 2-hour calls. In addition, the CF-PR and CF-PCMH were reviewed by two separate TEPs for usability. In total, five TEPs were convened for this work.

Results: While retaining much of the CFIR's original structure and most of its original concepts, the revised frameworks address distinctive features of each of the three interventions. We added concepts relevant to each topical area, used terminology that aligns more closely with research in each area, and more explicitly addressed the iterative and interactive nature of complex system change. Many of the newer elements were integrated across two or more of the frameworks. Two new domains were added to each of the frameworks for intermediary outcomes related to the implementation and outcomes of the interventions themselves. Several CFIR domains and constructs were renamed to be more resonant with the intervention's research target group. None of the original CFIR constructs were dropped, but several dozen new constructs were added across the three new frameworks. As these were iterative products, with initial process redesign and PCMH frameworks informing Care Transitions, many of these new constructs overlap. Nearly all the definitions of the CFIR constructs were modified to some extent to incorporate terminology and examples tailored to the specific interventions.

Conclusions. These contextual frameworks provide a foundational taxonomy and conceptualization of key implementation constructs that researchers can use across studies to enhance their comparability and synthesis, thereby better informing the generalizability and scalability of specific interventions. In adapting the CFIR for complex system interventions, it is critical to include research and practice stakeholders to ensure the content is understandable and applicable to the studies of interest.

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Executive Summary

Background

In January 2012, the RTI International–University of North Carolina at Chapel Hill Evidence-based Practice Center (RTI-UNC EPC) initiated a project to develop integrative contextual frameworks that would guide implementation research on two types of complex systems of intervention: process redesign for improved efficiency and reduced costs, and Patient-Centered Medical Homes (PCMH). Under a follow-on contract initiated in September 2012, a similar effort was launched for Care Transitions between hospital and ambulatory care settings. These three interventions are supported by AHRQ in its research portfolio as an investment in strategies that hold the potential to improve health care and delivery.

Investigators can use the contextual frameworks to examine in depth the conditions under which implementation occurs and the multitude of factors (and the complex web of relationships among them) that determine whether the intended outcomes are achieved. In short, these contextual frameworks bring to the fore *how, why, where,* and *for whom* an intervention succeeds or fails. Equally important, these contextual frameworks offer a general taxonomy and conceptualization of key implementation constructs. Used as a sort of universal guide by investigators engaged in similar fields of study, these contextual frameworks could enhance the comparability of these studies and the synthesis of their findings. Intervention designers, implementers, and decisionmakers will gain a greater understanding of the generalizability and scalability of specific interventions.

Scope

The three contextual frameworks presented here build upon previous work. We identified the Consolidated Framework for Implementation Research (CFIR)[1] as a practical model amenable to adaptation for complex systems intervention research. The CFIR is a general model of implementation synthesized from 19 different models and frameworks and can guide a broad range of intervention research. It consists of four domains that describe the internal and external context of implementation: Intervention Characteristics, Outer Setting, Inner Setting, and Process. As part of this effort, we convened a Technical Expert Panel (TEP) to critically assess the suitability and fit of each CFIR component to the specific research and evaluation requirements of each of the three interventions. Using the input of the TEP as well as the findings of a brief literature update, we modified the elements of the CFIR (e.g., definitions, terms, organization, and structure) to enhance usability and relevance.

Methods

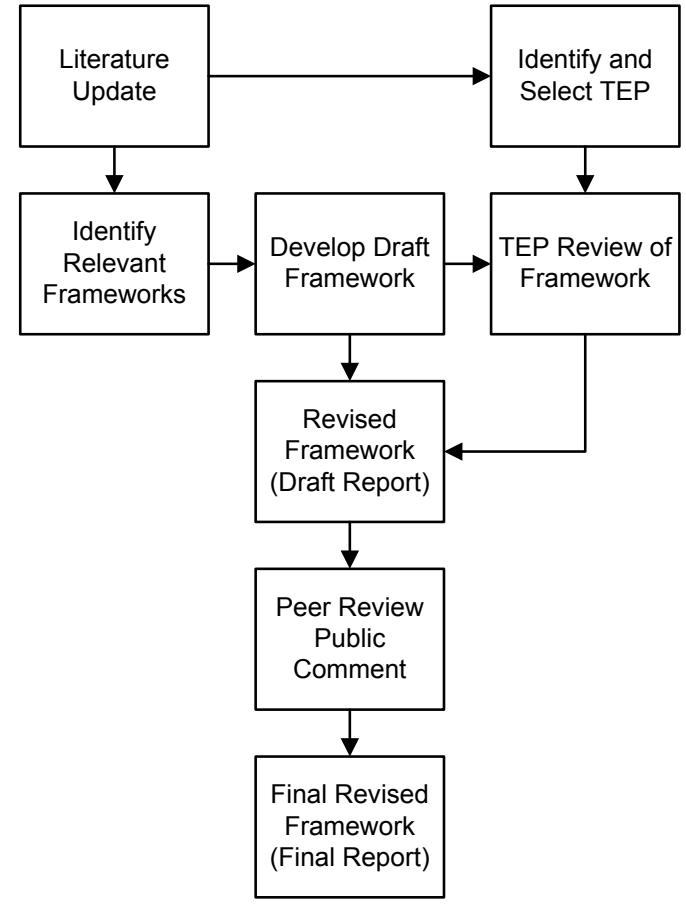
In this section, we briefly describe the four methods used for the adaptation and refinement of: (1) a brief literature scan, (2) TEPs to inform the content and use of each of the three draft contextual frameworks, (3) TEPs to inform the usability of modified frameworks, and (4) a self-assessment of the first phase project.

The work was carried out in two discrete phases: phase 1 (January 2012 through June 2012) and phase 2 (September 2012 to present). In phase 1, we developed the draft Contextual Framework for Process Redesign (CF-PR) and Contextual Framework for PCMH (CF-PCMH). In phase 2, we conducted a self-assessment of phase 1, refined the CF-PR and CF-PCMH, and

modified the process for the adaptation of the Contextual Framework for Care Transitions (CF-CT). The project's time frame did not allow for a TEP to assess the usability of the CF-CT.

Framework adaptation is a sequential process that iteratively builds on the input from a set of sequential activities as depicted in Figure ES-1. The first activity, the literature update, informs the initial draft of the adapted framework, which will be subsequently revised using the feedback from the TEP and then finalized through the input of peer reviewers and public comments.

Figure ES-1. Contextual framework development



Abbreviations: TEP = Technical Expert Panel.

Literature Scan

Each scan of the literature began with a search after the publication date of the CFIR to identify relevant topic-specific contextual and theoretical frameworks. A general set of questions guided the abstraction of the included articles. The investigative team used the results of the literature scans to develop the two primary components of each framework: a graphical representation and a table listing domains and constructs, their definitions, and examples (for selected constructs). The questions for the Care Transition abstraction were tailored to identify content not already captured in the adapted frameworks.

TEPs

We convened two TEPs in 2012, one each for process redesign (8 members) and PCMH (7 members). Individuals recruited to each TEP included researchers with extensive experience in

one or more of the following three areas relevant to the intervention: research and evaluation, management and practice, and general implementation research. A similar protocol was followed to recruit the 11-member Care Transition TEP convened in 2013. We sought to include individuals with a range of professional perspectives. These subject matter experts were identified through the literature scan, AHRQ project officers, and the experts themselves, who recommended colleagues to the team.

Two additional TEPs evaluated the usability of the CF-PR and CF-PCMH frameworks. Because the focus was on the usability of the framework, the membership of these TEPS differed from the first round. We recruited TEP members who represented researchers as well as health care executives and providers who would be potential users of the frameworks. The process redesign usability TEP had 5 members and the PCMH usability TEP had 6 members.

Self-Assessment

In addition to receiving feedback from the usability TEPs, we conducted a self-assessment of the initial phase of the project, prior to initiating the Care Transitions adaptation. The purpose of the self-assessment was twofold: to further the development of the CF-PR and CF-PCMH, and to apply the lessons learned from the initial work to the Care Transitions effort.

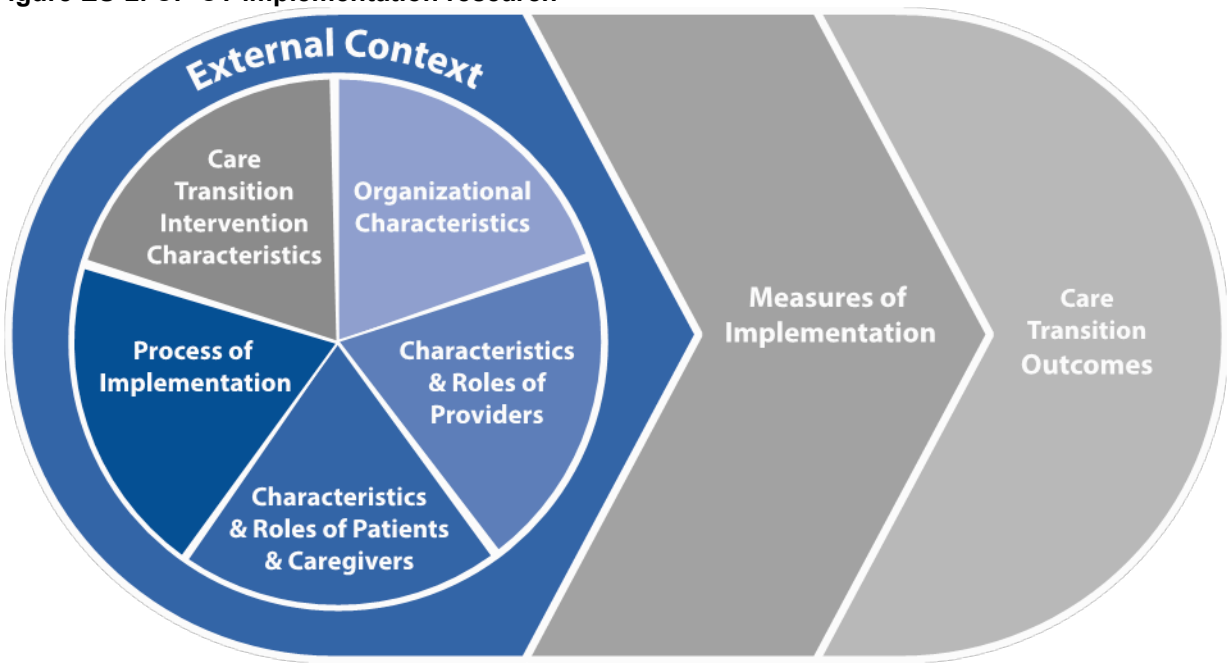
Upon deliberation, we selected a set of recommendations that were feasible to complete within the time frame of this project. These included the majority of suggestions made by the TEPs; only a few suggestions (such as moving the frameworks online) were not addressed. In addition to making changes to the original versions of the CF-PR and CF-PCMH, we used these recommendations as we developed the CF-CT.

The Adapted Contextual Frameworks

The three adapted contextual frameworks maintained many of the essential elements of the CFIR; although a number of domains and constructs (sub-elements of a domain) were renamed, none of the constructs were dropped entirely. A number of the noteworthy modifications include:

- The addition of a "Measures of Implementation" domain to describe the quality or success of the implementation.
- The addition of an outcomes domain. The outcomes vary by intervention although they share some similarities, particularly between the CF-PCMH and CF-CT.
- The addition of a patient domain to the CF-CT graphic. Some TEP members felt the frameworks could better highlight patient needs, preferences, and characteristics and recommended separating the patient from the provider characteristics. The PCMH TEP also thought the framework could emphasize the patient more strongly, but did not recommend creating a separate domain for patients and caregivers.
- Reconceptualization of the CFIR graphic. The original CFIR graphic attempted to convey the dynamic and permeable interaction between the five CFIR domains (Intervention Characteristics, Inner Setting, Outer Setting, Characteristics of Individuals, and Process). The TEPs' input led us to reconceptualize the graphic and add implementation and outcomes domains. Figure ES-2 presents the final graphic for the CF-CT, which is similar to the graphics for the CF-PR and PCMH and the farthest departure from the original CFIR. The CF-CT drops the term "settings" and highlights patients and providers as discrete entities.

Figure ES-2. CF-CT implementation research



- Several dozen new constructs were added as part of the adaptation. Many of these new constructs overlap, as the frameworks were developed iteratively. About half of the new constructs are the result of adding the implementation and outcome domains. These new constructs and subconstructs are further detailed in Table ES-1.

Table ES-1. New framework constructs

Domain Construct /*Subconstruct*	**CF-PR**	**CF-PCMH**	**CF-CT**
Intervention Characteristics	—	—	—
Vision and change strategy	✓*	✓	✓
Feasibility	✓	✓*	✓
Compatibility	✓*	✓	✓
Radicalness	✓*	✓	✓
User control	✓*	✓	✓
Workflows	✓*	✓	✓
Task/process standardization	✓*	✓	✓
History	✓	✓*	✓
Location of PCMH activity (location of intervention activity in CF-CT)	—	✓*	✓
Outer Setting (External Context in CF-CT)	—	—	—
Technological environment	✓*	✓	✓
Population needs and resources	—	✓*	✓
Community resources	—	✓	✓*
Inner Setting (Organizational Characteristics in CF-CT)	—	—	—
Staff commitment	✓*	✓	✓
IT and HIT resources	✓*	✓	✓
Human factors (*HIT/IT accessibility* in CF-PCMH)	✓*	✓	—
Other resources	✓	✓*	✓
Training and education	✓*	✓	✓
Patient centeredness	—	✓*	✓
Measurement capability and data availability	✓	✓	✓*

(continued)

Table ES-1. New framework constructs (continued)

Domain Construct /*Subconstruct*	**CF-PR**	**CF-PCMH**	**CF-CT**
Patient self-management infrastructure	—	✓*	✓
Continuity	—	✓	✓*
Characteristics of Individuals and Teams (Characteristics and Roles of Providers and Patients in CF-CT)	—	—	—
Skills and competencies	✓*	✓	✓
Role	✓	✓*	✓
Authority	✓	✓*	✓
Collective efficacy	✓	✓*	✓
Socioeconomic demographics	—	✓	✓
Patient needs and resources	✓	✓	✓*
Caregiver needs and resources	—	✓	✓*
Process of Implementation	—	—	—
Assessing	✓	✓*	✓
Contingency planning	✓	✓*	✓
Acquiring/allocating new resources	✓	✓*	✓
Process ownership	✓	✓	✓
Engaging/relationships between organizations, external context	✓	✓	✓*
Organizational leaders	✓	✓*	✓
Frontline staff	✓	✓*	✓
Facilitator	✓	✓*	✓
Integrators	—	—	✓*
Patients and other stakeholders	✓	✓*	✓
Decision making	✓	✓*	✓
Staging and iteration	✓*	✓	✓
Measures of Implementation	—	—	—
Acceptability	✓	✓	✓
Adoption/abandonment	✓	✓	✓
Appropriateness	✓	✓	✓
Implementation cost	✓	✓	✓
Fidelity	✓	✓	✓
Reach	✓	✓	—
Reach within the population	✓	✓	✓*
Reach within the organization	✓	✓	✓*
Penetration	✓	✓	✓
Replicability	✓	✓	✓
Sustainability	✓	✓	✓
Evolvability	✓	✓	✓*
Outcomes	—	—	—
Cost effects/impact	✓*	✓	✓
Perceived value	✓*	✓	✓
Unintended consequences	✓	✓*	✓
Processes of care	—	✓*	✓
Patient-centered	—	✓*	✓
Coordinated	—	✓*	✓
Comprehensive	—	✓*	✓
Accessible	✓	✓*	✓
Quality	✓	✓*	✓
Safety	✓	✓*	✓
Effectiveness	✓	✓	✓
Timeliness	✓	✓	✓
Efficiency	✓	—	—

(continued)

Table ES-1. New Framework Constructs (continued)

Domain Construct /*Subconstruct*	CF-PR	CF-PCMH	CF-CT
Patient and caregiver-centered outcomes	—	✓	✓*
Patient/caregiver experience	✓	✓*	✓
Provider experience	✓	✓*	✓
Clinical outcomes	—	✓*	✓
Health care utilization	✓	✓*	✓

*Indicates the original source of the construct or subconstruct.

Abbreviations: CF-CT = Contextual Framework for Care Transitions; CF-PCMH = Contextual Framework for Patient-Centered Medical Homes; CF-PR = Contextual Framework for Process Redesign; HIT = health information technology; IT = information technology; PCMH = Patient-Centered Medical Home.

Discussion

Capturing the context of complex system interventions can be daunting, especially because we lack a common taxonomy to describe and understand how the interplay of people, settings, technology, and policy may affect some desired outcome or impact. AHRQ identified the CFIR, adapted to the requirements of three types of complex system interventions, as a potential solution to this dilemma. The CFIR draws from a wide range of disciplines and theories but does not posit any particular set of hypotheses or causal pathways and is thus theoretically agnostic. This feature makes it suitable for the study of complex system interventions, which inherently benefit from a multidisciplinary approach. The CFIR's broad range of constructs encompass most of the contextual dimensions of the three interventions we adapted.

Using the CFIR to conceptualize the multiple layers of interactions and networks that characterize complex system interventions was difficult because many of the elements of context can vary by time, location, and organizational unit (e.g., individual, team, practice, organization, system). The adapted frameworks in their current form, confined to text-based two-dimensional tables, do not lend themselves to the levels of abstraction possible with complex systems. A Web-based tool that allows the user to explore the organizational hierarchies within a construct and juxtapose them against two or more dimensions (e.g., organizational unit by location) may come closer to achieving the original intent of our two-dimensional tables.

The adapted frameworks should acquaint the researcher or the implementing organization with the large range of contextual variables that are possible and important to consider in a study or evaluation. However, we recognize that the sheer number of constructs can be overwhelming and at the TEPs' suggestion we added a general roadmap to guide the construct selection process. As every study is unique, there is no simple recipe for construct selection. The decision to include or leave out specific constructs should be rooted in the context of the study itself.

Cross-Cutting Issues

The TEPs raised a number of conceptual challenges specific to their intervention area, but a number of the issues they noted are cross-cutting and are likely to arise in any similar exercise to describe and conceptualize the context of implementation. These issues include:

- *Components of the intervention.* A complex system intervention can include an overall redesign strategy (e.g., applying Lean/Toyota Production Systems), tactics (e.g., process mapping), and specific projects (e.g., conducting a rapid cycle improvement exercise to improve patient throughput in clinic). Researchers will have to decide where to focus their attention (e.g., organization-wide initiative, tactics, or projects).

- *Component of the intervention vs. target of the intervention*. Elements of the contextual frameworks that are usually thought of as the context within which the intervention occurs can also become the targets of an intervention (e.g., climate, leadership).
- *Bundled nature of interventions.* The interventions can have multiple components (e.g. practice facilitator coupled with a case manager to coordinate care); a key aim for evaluators is assessing which parts of the bundle were implemented, which parts are associated with outcomes, and the relative importance of the components.
- *Intervention timing and research time frame*. The meaning and relevance of constructs are likely to change across stages of implementation. Researchers who follow an intervention over time might retain some core constructs across the entire study but select others that apply chiefly to one stage in the life course of the intervention. Moreover, implementation may be more of an iterative process than a linear one that proceeds sequentially through clear stages.
- *Organizational units and level of analysis. C*omplex system interventions operate at multiple organizational levels (i.e., levels of analysis). Relevant levels may include individual participants, teams, units, organizations (including autonomous practices), and delivery systems. The frameworks may inform research by alerting researchers to the following:
    - The importance of conceptualization and measurement at appropriate levels of analysis and attention to and conceptualization of interactions across levels of analysis and among actors at the *same* level. Several TEP members noted that interactions among elements within the framework may be as important as the effects of isolated variables.
    - The importance of weighing potential contributions of multilevel analysis against the need to keep the research within manageable proportions.
- *Stakeholder and practice roles.* The CFIR distinguishes among many practice roles, and our discussion with the TEPs led to the addition of yet other roles. We recognize that constructs may take on different meanings or measured values when applied to different roles.
- *Conceptualizing the framework around settings or organizations.* Complex system interventions may be broader than a particular practice or integrated health care setting (where patients receive care and treatment) and can include community-based organizations, such as community coalitions, agencies, and collaboratives. These are often the effector arm and critical to Care Transitions or PCMH interventions. Hence, interventions may be based upon layers of organizations, rather than embedded in a single setting or group of settings.
- *Patient-centered/population health perspectives.* A number of the PCMH and Care Transitions TEP members thought the draft contextual frameworks could be more patient-centered. However, some members of the Care Transitions TEP pointed out that institutional outcomes such as readmissions and cost, rather than patient-centered outcomes such as quality of life, may be a dominant goal. Another consideration for context is the influence of population health on the intervention design and outcomes.
- *Applicability of contextual frameworks to practice*. Although originally designed to guide research and evaluation, the CF-PCMH could also incorporate issues of concern to practitioners and managers and has the possibility of becoming a useful tool for practice.

Conclusion

The investigative team took a very open approach to this effort, beginning with a literature scan, discussions with the Agency, and our TEP. Much of the adaptation protocol was developed during the project and we offer here guidance to other researchers wishing to make similar adaptations of the CFIR.

- **Involve the developers of the framework and those familiar with it.** In our case, we invited one of the developers of the CFIR to present the framework to the TEPs. This individual's participation was especially helpful in orienting the investigative team and the TEPs to the purposes, intent, and application of the framework.
- **Conduct a literature scan and give it a clear focus**. A full systematic review of the intervention is neither necessary nor appropriate for framework adaptation. A brief scan of the literature to uncover any relevant work since the publication of the CFIR was sufficient for our purposes. We also relied on the TEP to alert us to relevant literature we may have missed in the formal scan. As experts in their fields, TEP members are in the best position to know which contextual factors really matter for their research.
- **Have a TEP.** The input of the TEP was supremely important in alerting the team to conceptual challenges and nuances that could not have been gleaned from the literature alone. Moreover, the team could not have assessed the potential utility of the frameworks without TEP involvement.
- **Include TEP members with a variety of roles and perspectives.** We recruited TEP members who represented research, practice, funding agencies, health care management, and policy (i.e., associations). The diversity of opinions created rich dialogue and likely brought to light issues that would not have been raised by a group with a more homogenous composition.
- **Have criteria for assessing framework utility and effectiveness.** The team found Gerring's criteria[2] for concept formation (i.e., familiarity, resonance, parsimony, coherence, differentiation) extremely useful in eliciting specific feedback on what TEP members liked or did not like about the framework.
- **Use simple graphics.** The investigative team and the TEP felt that some adaptation of the CFIR graphic was warranted. Complex system interventions by their very nature do not lend themselves to simple graphics; it took multiple iterations to arrive at the final versions presented here.
- **Apply the adapted framework to a case study**. A framework or model is an abstraction, a tool for organizing and making meaning out of a complex idea or enterprise. The team used the case studies to good effect in uncovering those elements of the framework that needed additional refinement or simply did not align to current thinking.

The goal of adaptation is not perfection, and care must be taken not to make a framework "endlessly complex"[1] for the sake of completeness. We encourage researchers to approach the adaptation process, and the frameworks themselves, iteratively and to document and share their experiences with colleagues. Our collective understanding of the complex phenomena we are striving to define, measure, and explain can only increase through such efforts.

Introduction

Background

In January 2012, the Agency for Healthcare Research and Quality (AHRQ) contracted with the RTI International–University of North Carolina at Chapel Hill Evidence-based Practice Center (RTI-UNC EPC) to develop integrative contextual frameworks that would guide implementation research on two types of complex systems of intervention: process redesign for efficiency and reduced cost, and Patient-Centered Medical Homes (PCMH). Under a follow-on contract initiated in September 2012, a similar effort was launched for Care Transitions between hospital and ambulatory care settings. These three interventions are supported by AHRQ in its research portfolio as an investment in strategies that hold the potential to improve health care and delivery.

The focus on complex system interventions is part of AHRQ's ongoing effort to bring new and useful perspectives to bear on how researchers conceptualize health care organization and delivery. In its report *Crossing the Quality Chasm*,[3] the Institute of Medicine put forth a case for incorporating the perspectives of complexity science, specifically Complex Adaptive Systems, in the design of health care interventions. The care systems which process redesign, PCMH, and Care Transitions seek to intervene upon bear many of the defining attributes and features of a Complex Adaptive System. These systems are "complex," meaning they are diverse both in their constituent parts and general form. They are capable of changing in response to feedback and experience and are thus "adaptive." Their structure aligns to that of a "system," which is a set of interdependent entities enmeshed and embedded within one another.

Context is a critical factor within this highly adaptive and dynamic environment because all potential confounding variables cannot be controlled through randomization and stratification to homogenous population. Even clinical interventions, tested under highly controlled settings, may eventually be scaled to settings and populations very unlike those in which they were originally tested. Therefore, the key question for any kind of intervention applied to a Complex Adaptive System is not only "does it work" but under what conditions and for which populations these interventions are more or less effective. Implicit in these questions is the notion that the context will change the intervention and vice versa. However, no common definition of context exists. Shekelle et al., speaking about patient safety practices, note that "There is no standard definition of 'context.' It may include detailed information about processes of implementation, as well as barriers and facilitators related to the organizational and policy environment in which a patient safety practice is implemented." [4, p.9]

We identified the Consolidated Framework for Implementation Research (CFIR)[1] as a practical model for furthering the definition and conception of context for complex systems interventions. The CFIR addressed the need of researchers and evaluators to assess the effectiveness of implementation within a specific context, and to not only maximize the benefit within that context but also promote dissemination to other contexts. Numerous theories of implementation and context existed in the literature but had differing and overlapping terminologies and constructs. The goal of the CFIR was to synthesize these various terminologies, definitions, and constructs into a consolidated framework and a common taxonomy for implementation research on health service delivery. Drawing on 19 different theories, the CFIR consists of four domains that describe the internal and external context of implementation: Intervention Characteristics, Outer Setting, Inner Setting, and Process. The

CFIR does not posit any particular set of hypotheses or causal pathways and is thus theoretically agnostic.[1]

The contextual frameworks described here and adapted from the CFIR are comprehensive, heuristic tools that researchers can use to generate novel and compelling questions, as well as to glean fresh insights for research and evaluation design. Investigators can use the contextual frameworks to examine in depth the conditions under which implementation occurs and the multitude of factors (and the complex web of relationships among them) that determine whether the intended outcomes are achieved. In short, these contextual frameworks bring to the fore *how, why, where,* and *for whom* an intervention succeeds or fails. Equally important, these contextual frameworks offer a general taxonomy and conceptualization of key implementation constructs. Used as a sort of universal guide by investigators engaged in similar fields of study, these contextual frameworks could enhance the comparability of these studies and the synthesis of their findings. Intervention designers, implementers, and decisionmakers will gain a greater understanding of the generalizability and scalability of specific interventions.

Scope

Our task was to build upon the CFIR, by examining its suitability and adapting it as necessary to the unique research and evaluation requirements of process redesign for efficiency and cost reduction, PCMH, and Care Transitions through literature scans and a series of intervention-specific Technical Expert Panels (TEPs). We assumed from the outset that some degree of adaptation would be required because the CFIR, as a general model of implementation, might not speak to the unique and distinct attributes of process redesign, PCMH, or Care Transitions. For each intervention, we used TEP input about enhancing usability and relevance to modify the CFIR (e.g., definitions, terms, organization, and structure).

Users of the resulting adapted contextual frameworks—the Contextual Framework for Process Redesign (CF-PR), Contextual Framework for Patient-Centered Medical Homes (CF-PCMH), and Contextual Framework for Care Transitions (CF-CT)—should view them as works in progress intended to evolve and adapt to the context in which they are applied.

Organization of the Report

The remainder of the report is composed of six chapters. The first of these is a general Methods chapter, which describes the general procedures for framework adaptation. The three chapters that follow present the CF-PR, CF-PCMH, and CF-CT, respectively. These chapters are organized similarly and present: (1) a brief overview of the intervention topic; (2) a brief summary of framework modifications; (3) the contextual framework itself, represented in a conceptual graphic and detailed table; (4) guidance for using the contextual framework; and (5) a case study application of the contextual framework. The chapters containing the contextual frameworks can be used as stand-alone documents and accordingly, readers should direct their attention to the contextual framework closest to their research interests. In the final two chapters, the Discussion highlights the cross-cutting conceptual and methodological issues the TEPs considered during the adaptation process, and the Conclusion presents recommendations for continued framework adaptation and refinement.

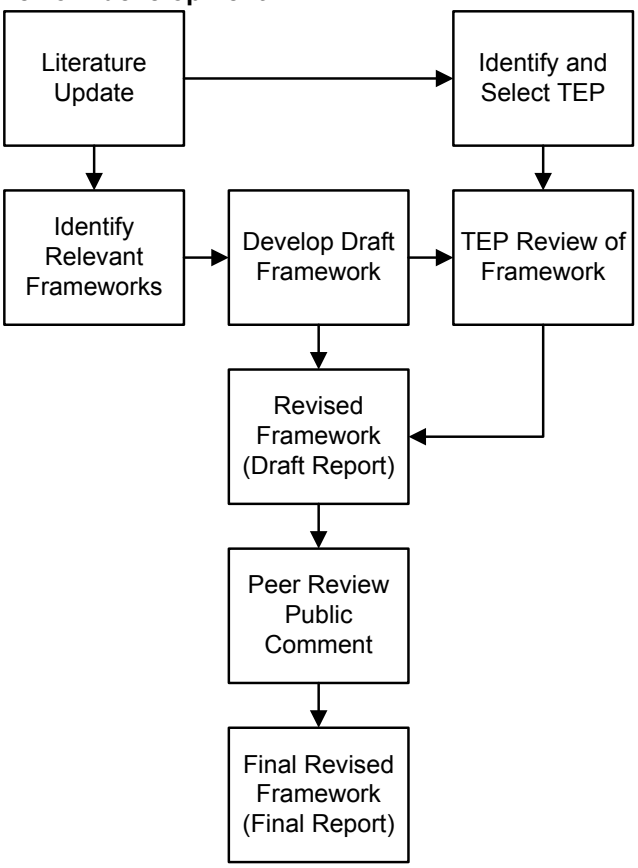
Methods

Adaptations of the Consolidated Framework for Implementation Research (CFIR) to process redesign for efficiency and reduced cost, Patient-Centered Medical Homes (PCMH), and Care Transitions were modified using the feedback obtained from a literature scan, consultation with the original CFIR developer and experts familiar with that work, and two Technical Expert Panels (TEPs) that examined the framework objectively during a series of calls. In this section, we briefly describe the four methods used for the adaptation and refinement of: (1) a brief literature scan, (2) TEPs to inform the content and use of each of the three draft contextual frameworks, (3) TEPs to inform usability of the Contextual Framework for Process Redesign (CF-PR) and Contextual Framework for Patient-Centered Medical Homes (CF-PCMH), and (4) a self-assessment of the first phase project.

The work was carried out in two discrete phases: phase 1 (January 2012 through June 2012) and phase 2 (September 2012 to present). In phase 1, we developed the draft CF-PR and CF-PCMH. In phase 2, we conducted a self-assessment of phase 1, refined the CF-PR and CF-PCMH, and adapted those procedures to the adaptation of the CF-CT. The project's time frame did not allow for a TEP to assess the usability of the CF-CT.

Framework adaptation is a sequential process that iteratively builds on the input from a set of sequential activities as depicted in Figure 1. The first activity, the literature update, informs the initial draft of the adapted framework, which will be subsequently revised using the feedback from the TEP and then finalized through the input of peer reviewers and public comments.

Figure 1. Contextual framework development



Abbreviations: TEP = Technical Expert Panel.

Upon deliberation, we selected a set of recommendations that were feasible to complete within the time frame of this project. These included the majority of suggestions made by the TEPs; only a few suggestions (such as moving the frameworks online) were not addressed. In addition to making changes to the original versions of the CF-PR and CF-PCMH, we used these recommendations as we developed the CF-CT.

Literature Scan

The adaptation process for each of the intervention-specific frameworks began with a scan of the literature published several years prior to the CFIR's 2009 publication to identify relevant topic-specific contextual and theoretical frameworks that may not have been covered in the CFIR. **Appendix A** details the number of articles identified and then selected for review and abstraction.

The investigative team used the results of the literature scans to develop the two primary components of each framework: a graphical representation and a table listing domains and constructs, their definitions, and examples (for selected constructs).

Content and Use TEPs

We recruited three TEPs, one each for process redesign for efficiency and cost reduction (8 members), PCMH (7 members), and Care Transitions (11 members), to assess the content and use of the draft contextual frameworks. Individuals recruited to each TEP included those with extensive experience in the intervention in one of the following three capacities: research and evaluation, management and practice, or general implementation research. The goal of TEP recruitment was to include individuals with diverse professional perspectives and ensure representation in these three capacity areas. For the Care Transitions TEP, we also sought to include key organizations involved in Care Transitions interventions and initiatives—ReEngineered Discharge (RED), State Action on Avoidable Rehospitalization (STAAR), and the Community-Based Care Transitions Program (CCTP). These subject matter experts were identified through the literature scan, AHRQ project officers, and the experts themselves, who recommended colleagues to the team. For each topic, we held two rounds of TEP conference calls, with each group call lasting 2 hours. We held 1-hour individual calls with experts who were not available for the group calls.

Input from the PCMH TEP was used to refine the CF-PR and vice versa. Working in tandem, the TEPs identified issues that might not have been raised by each TEP on its own and produced greater depth and breadth of input for the adaptation process.

Usability TEPs

In a second phase of this project, we evaluated the usability of the CF-PR and CF-PCMH by convening two new TEPs, one each to assess the process redesign and PCMH frameworks. Because the focus was on usability, the membership was different from the previous TEPs. We sought TEP members who represented researchers, health care executives, and providers who would be potential users of the frameworks. The process redesign usability TEP had 5 members, and the PCMH usability TEP consisted of 6 members. Following similar procedures to the previous TEPs, each usability TEP met twice and members discussed the effectiveness and ease of use of the CF-PR and CF-PCMH, and then applied the frameworks to a case study. Details on

the composition of the usability TEP are provided in **Appendix B** and the TEP recommendations in **Appendix C.**

Self-Assessment

During the second phase of the project, we conducted a self-assessment early on to apply lessons learned to the Care Transitions TEP and to gather final recommendations for the CF-PR and CF-PCMH. The self-assessment included a self-assessment questionnaire we emailed to the initial TEP members to gather feedback on the procedures and materials we had used during their calls. In addition, a member of the investigative team not involved in the first phase reviewed the procedures and materials for clarity and effectiveness in meeting TEP aims.

Peer and Public Review

Experts in the process redesign for efficiency and cost reduction, PCMH, and Care Transitions fields and individuals representing stakeholder and user communities will be invited to provide external peer review of this report, and AHRQ and an associate editor will also provide comments. The draft report will be posted to the AHRQ website for 4 weeks to elicit public comment. We will address all reviewer comments, revise the text as appropriate, and document the items in a disposition of the comments report.

Contextual Framework for Process Redesign Interventions

Overview

Process redesign involves changing the way care is delivered by "conceptualizing, mapping, refining, and continuing to improve the many processes of healthcare." Further, redesign may "challenge existing practices, data structures, roles, and management practices, and it results in continuous change."[3] The focus of our work was to develop an integrative contextual framework that would guide implementation research on process redesign for efficiency and cost reduction (CF-PR). A few examples of these kind of interventions could include changes to an office or clinic workflow to allow administrative tasks to be carried out more easily and with less time, the introduction of new equipment or technology to improve clinical procedures, or streamlining billing procedures.

The purpose of this CF-PR is to guide research and evaluation of process redesign implementation within a broad range of organizational settings. The primary users of this framework are investigators and practitioners who wish to understand why implementation succeeds or fails and whether the process redesign intervention or its components can be replicated and scaled to other settings. Investigators can apply the CF-PR to a whole intervention with various distinct parts or to one or more those parts.

This chapter is organized into six sections. The first, the Organization of the CF-PR section, describes briefly the domains of the CF-PR. Following this section is Modifications to the CF-PR, which summarizes the most noteworthy changes that CF-PR made to the Consolidated Framework for Implementation Research (CFIR) to adapt it to research on process redesign. The CF-PR is presented in two forms—a graphic followed by a detailed table. The How to Use the CF-PR section gives users a step-by-step roadmap for approaching the multiple and complex dimensions laid out in the table. This chapter concludes with a case study of a process redesign implementation that applies the CF-PR using the how-to steps presented earlier.

Organization of the CF-PR

Tables 1 through 7 show the entire CF-PR for efficiency and waste reduction. The CFIR domains,[1] summarized with their respective constructs and definitions in the first two columns of Tables 1 through 7, include:

- **Process Redesign Intervention Characteristics:** The characteristics of the intervention being implemented into a particular organization, including core components (the essential and indispensable elements of the intervention itself) and an adaptable periphery (adaptable elements, structures, and systems related to the intervention and organization into which it is being implemented).
- **Outer Setting**: Includes the economic, political, and social context within which an organization resides.
- **Inner Setting:** Tangible and intangible manifestation of characteristics of the organizations involved in the intervention, including structural characteristics, networks and communications, culture, climate, and readiness that all interrelate and influence implementation.

- **Characteristics of Individuals/Teams Involved**: The individuals (as carriers of cultural, organizational, professional, and individual mindsets, norms, interests, and affiliations) involved with the intervention and/or implementation process. Includes patients and caregivers.
- **Process of Implementation**: As used here, this term refers to the course of *actions* (e.g., planning, engaging, and reflecting) to achieve individual- and organizational-level use of the intervention, as designed.
- **Measures of Implementation Success**: These elements refer to what Proctor et al.[6] call "implementation outcomes"; they are intermediary outcomes that describe how well the implementation was carried out and the prospects for sustainability.
- **Process Redesign Outcomes**: The results of the process redesign implementation, defined as the targets of the process redesign intervention.

The top-tier domains (presented above) represent families of constructs, and we have subdivided these into more precise categories of subconstructs. Constructs labeled "new" were not present in the original CFIR. Users of the framework may find it useful to refine these subconstructs even further for specific research purposes. In their current states, the original CFIR and our CF-PR both provide comprehensive menus of contextual domains and constructs. Researchers could use these frameworks to define and review the range of potentially relevant concepts and variables as they prepare an implementation study. Additionally, they may engage in prestudy to determine which constructs are likely to be most useful. During their research, they may refine their selection of constructs and their specifications of them in response to data that emerge from the field or in response to changes in the intervention process and context that take place during the life course of the intervention.

Modifications in the CF-PR

The CFIR served as the foundation from which the CF-PR was developed. In addition the CF-PR and CF-PCMH were developed simultaneously, and therefore additions to one framework resulted in similar additions to the other when appropriate. All construct and subconstruct additions are noted in Table ES-1. Descriptions and examples of the original CFIR have been modified to enhance their resonance to process redesign researchers and evaluators. Below, we briefly list the constructs, by domain, that were added to the CF-PR based on the input of the process redesign TEP or our review of the process redesign literature. For definitions of these constructs, we direct the reader to the CF-PR tables which follow.

- Intervention Characteristics: The CF-PR includes the following new constructs reflecting characteristics of a process redesign intervention which often focuses on changing a process involving technology and/or workflow: *vision and change strategy, feasibility, compatibility, radicalness, user control, workflows, task selection for standardization, task/process standardization*.
- Outer Setting: *Technological environment* is a new construct added to the CF-PR and reflects the importance of technological trends and updates in the development and implementation of a process redesign intervention.
- Inner Setting: The CF-PR includes a few new constructs related to features of the inner setting that may impact the process redesign evaluation. These are *staff commitment* (a subconstruct under *readiness for implementation), information technology (IT) and health information technology (HIT) resources, human factors, training and education.*

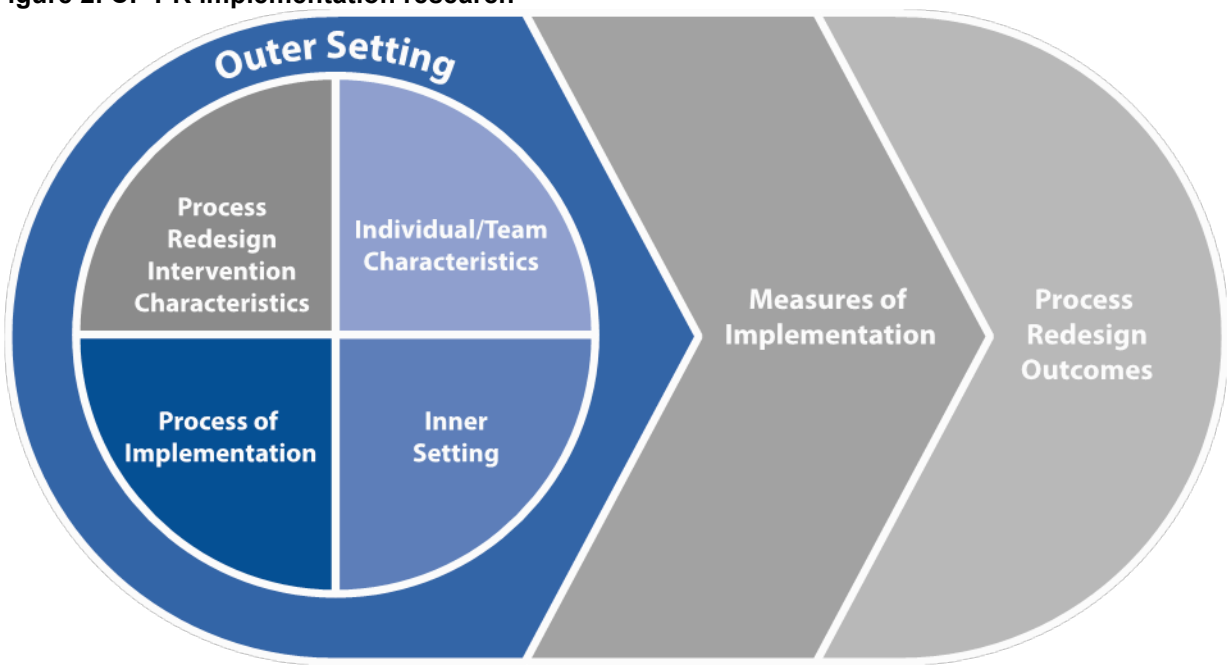
In addition, we included a construct for *other resources* to reflect that there may be resources specific to a process redesign intervention not captured in specific constructs.

- Process of Implementation: We defined the *executing* construct with more detail, adding *staging and iteration* as a subconstruct.
- Process Redesign Outcomes: In order to provide users with a comprehensive list of outcomes related to process redesign, we included the following constructs: *cost effects/impact, perceived value.* Furthermore, we capture the aims outlined by the Institute of Medicine in their seminal 2002 report by including the following outcomes: *safety, effectiveness, timeliness, efficiency, equitable.*

Graphic Representation of the CF-PR

Figure 2 is a graphic representation of the CF-PR. It shows the relationships of five of the domains to measures of implementation success and various process redesign outcomes. On the left side of the figure, the five domains are shown in a circle. The inner part of the circle is divided into four sections, representing each of the following domains: Process Redesign Intervention Characteristics, Individual/Team Characteristics, Inner Setting, and Process of Implementation. The outer ring encircles the inner ring, and represents the Outer Setting. The five domains flow into the measures of implementation success, which in turn affects the process redesign outcomes.

Figure 2. CF-PR implementation research

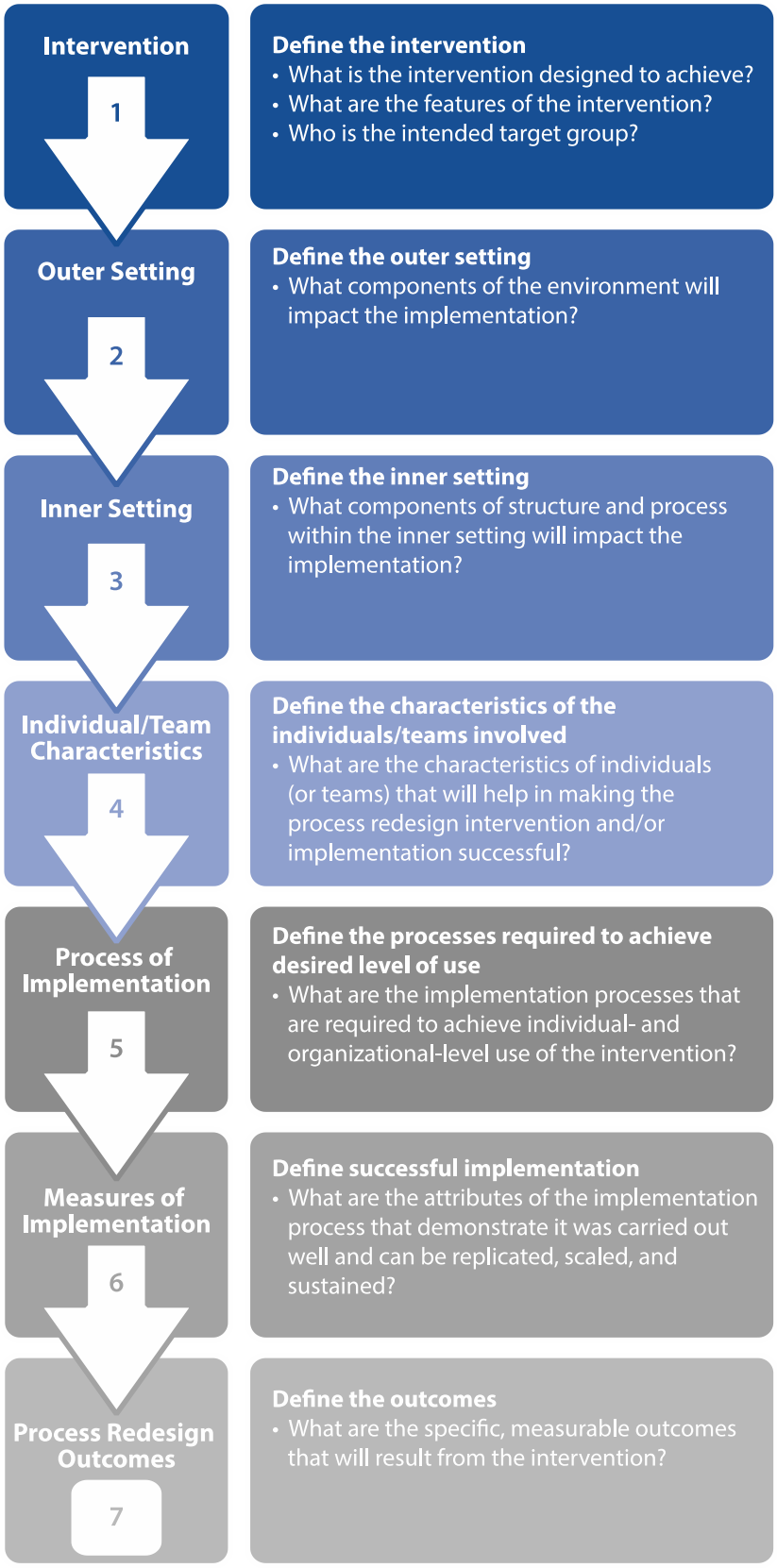


How to Use the CF-PR

The flowchart in Figure 3 presents step-by-step guidance on how the CF-PR may be used. The flowchart presents a series of questions, and each series is tied to a particular domain in the framework (Tables 1 through 7). As these questions are considered, the user should refer to the appropriate domain in the framework table to see which constructs are relevant. For example, Step 1 corresponds to the intervention domain, and as users consider the various issues related to

this domain, they should refer to the framework to choose those constructs relevant to them. As mentioned previously, we do not prescribe which constructs must be selected due to the diversity of research objectives and to variations between different process redesign interventions. While following this step-by-step process of using the framework, we recommend that users of the framework select qualities, features, or characteristics that are closely tied to intervention outcomes.

Figure 3. How to use the CF-PR



Abbreviations: CF-PR = Contextual Framework for Process Redesign.

The CF-PR

Here we present the CF-PR in Tables 1 through 7 with brief definitions of the constructs and subconstructs, and examples. Constructs labeled "new" are additions to the original CFIR.[1] Based on TEP input, we added clarifying examples for those constructs and subcontracts that were unclear or complex. Each construct or subconstruct is independent and should be applied as appropriate to the research questions and objectives.

Table 1. CF-PR—I. PR Intervention Characteristics

Construct	Description	Examples
A. Vision and change strategy (NEW)	The proposed changes envisioned by the process redesign and the theory of change: how the intervention is supposed to work, what it is meant to achieve/do, and how it is to be executed and articulated through logic models, stated goals, objectives performance measures.	—
B. Targeted groups	The staff and others (vendors, patients) who will be impacted by the intervention.	—
C. Intervention source	Identifying who (which individuals or groups) originated the process redesign initiative, and/or from which source the components of the initiative were derived.	—
D. Evidence strength and quality	Target group and other stakeholders' perceptions of the quality and validity of evidence supporting the belief that the process redesign will have the desired outcomes.	Peer-reviewed, published literature. Guidelines from the National Quality Forum.
E. Relative advantage	Target group and other stakeholders' perception of the advantage of implementing process redesign instead of other possible interventions.	—
F. Adaptability	Target group and other stakeholders' perception of the degree to which process redesign strategies, techniques, and practices can be adapted, tailored, refined, or reinvented to meet local needs.	—
G. Feasibility (NEW)	Target group and other stakeholders' perception of the extent to which the process redesign can be successfully used or carried out within a given organization or setting.	—
H. Trialability	Target group and other stakeholders' perception of the ability to test components of the process redesign on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted.	—
I. Complexity	Target group and other stakeholders' perception of the perceived difficulty of implementation, reflected by duration, scope, centrality, and intricacy and number of steps required to implement.	—
J. Compatibility (NEW)	Target group and other stakeholders' perception of alignment of the meaning, values, and norms attached to process redesign with those held by members of the practice or organization.	—

(continued)

Table 1. CF-PR—I. PR Intervention Characteristics (continued)

Construct	Description	Comments and Examples
K. Radicalness (NEW)	Target group and other stakeholders' perception of the degree of difference between the change envisioned and the current state.;.[7]	—
L. User control (NEW)	End users' authority/skill to fix a problem on their own.	—
M. Workflows (NEW)	Tasks and workflows, including interdependencies between them that are the focus of the change strategy or that will be affected by it.	—
N. Task /process standardization (NEW)	Degree to which the process redesign seeks to standardize selected tasks and/or processes that require iterative consultation.	—
O. History (NEW)	Experiences with similar interventions within the setting and within the target population.	The maturity, breadth, and depth of QI activities within the unit/organization.[8,9]

Table 2. CF-PR—II. Outer Setting

Construct	Description	Examples
A. External networks	Degree to which an organization is networked with other external organizations that are engaged in similar types of process redesign development activities. *(Termed "cosmopolitanism" in the CFIR)*	—
B. External pressure	Pressure emanating from outside the organization to implement a process redesign intervention.	Key peer or competing organizations have already implemented process redesign; there is competitive pressure to secure a better share of the market.
C. External policy incentives/disincentives	Policies and regulations (governmental or other central entity), external mandates, recommendations and guidelines, and payment schemes that promote or hinder the adoption of process redesign.	—
D. Technological environment (NEW)	Technological trends and movements and the availability of technological innovations that may affect the intervention and its context.	Examples: software product trends, health information exchanges, cloud computing, social media mobile applications.

Table 3. CF-PR—III. Inner Setting

Construct	Description	Examples
A. Structural characteristics	Social architecture; age; maturity; size; mix of occupations of team, unit, organization, or system; and the employment status of physicians.	—
B. Teams and network characteristics	Influence, breadth, role diversity, depth, teams, networks of teams, and communication practices and protocols within and between teams. [9]	A practice or team's capacity for self-organization.
C. Culture	Norms, values, and beliefs within a team, unit, or practice that affect views of process redesign and its implementation.	—
D. Implementation climate	Capacity or reserve [10] for change and the shared receptivity of involved individuals to the intervention.	—
D1. Tension for change	Degree to which stakeholders perceive the current situation as intolerable or needing change.	—
D2. Mandate	Whether compliance with the process redesign initiative is expected.	—
D3. Accountability	Whether entities are subject to tangible consequences for noncompliance.	—
D4. Relative priority	Individuals' shared perception of the importance of the process redesign implementation within the organization.	—
D5. Organizational incentives	Extrinsic incentives offered to adopt process redesign.	Gain-sharing awards, promotions, increased stature, or respect.
D6. Learning climate	The organization's willingness to promote trial and error, test new methods, and innovate.	—
E. Readiness for implementation	Tangible and immediate indicators of organizational commitment to its decision to implement process redesign.	—
E1. Leadership commitment	Degree of commitment, involvement, and accountability of leaders and managers to quality and safety improvement in general, and to the process redesign initiative specifically.	—
E2. Staff commitment (NEW)	Degree of commitment, involvement, and accountability of physicians, nurses, and other staff to efficiency and waste reduction in general, and to the process redesign specifically.	Provider involvement in setting and monitoring efficiency targets.
F. Information access	Ease of access for staff to digestible, applicable information and knowledge about process redesign and its transmission through training and education.	—
G. IT and HIT resources (NEW)	Technological infrastructure in place to support electronic information management and redesign of patient care.	—
G1. HIT systems (NEW)	Electronic information management infrastructure and technologies available to clinicians to manage patient care, data, and communications.	Decision support tools, e-prescribing, electronic health records.
G2. IT systems (NEW)	Technological systems and capabilities to support process redesign.	Server space, bandwidth, interoperability, health information exchange.

(continued)

Table 3. CF-PR—III. Inner Setting (continued)

Construct	Description	Examples
G3. Human factors (NEW)	Human capabilities and limitations in the design of interactive systems of people, tools, equipment, technology, and work environments to ensure their safety, effectiveness, and ease of use.[11]	—
H. Measurement capability and data availability (NEW)	Availability or ability to obtain or calculate necessary data for monitoring, evaluation, and process improvement.	Data sharing, accountability for collection, documentation, analysis, and timeliness.
I. Training and education (NEW)	General level of resources dedicated to training and education available within the organization.	Online training tools, time given for training and education, funding for training.
J. Other resources (NEW)	Resources for implementation and ongoing operations to support change and innovation.	Physical space, equipment, staff time.

Abbreviations: CFIR = Consolidated Framework for Implementation Research; HIT = health information technology; IT = information technology; QI = quality improvement.

Table 4. CF-PR—IV. Characteristics of Individuals and Teams

Construct	Description	Examples
A. Knowledge and beliefs	Attitudes toward and value placed on the process redesign as well as their familiarity with facts, truths, and principles related to the intervention.	—
B. Skills and competencies (NEW)	Degree of relevant subject matter expertise, skills, and competencies within the implementing team, unit, and organization.	—
C. Role (NEW)	Individual's or team's role and responsibilities and extent of multiple or shared roles.	—
D. Authority (NEW)	Perceived and actual degree of authority to make decisions and act autonomously.[12]	—
E. Self-efficacy	Belief and confidence in their capacity to execute the courses of action necessary to achieve process redesign goals.	—
F. Collective efficacy (NEW)	Belief and conviction of individuals and teams involved that the process redesign transformation can be carried out in cooperation with others.[13]	—
G. Stage of change	Characterization of the phase an individual or team is in, as he or she progresses toward skilled, enthusiastic, and sustained application of process redesign strategies.	—
H. Identification with organization	How individuals or teams perceive the organization and their relationship and degree of commitment with that organization.	—
I. Socioeconomic demographics (NEW)	Characteristics related to the individual's socioeconomic status.	—
J. Patient Needs and Resources	Patient priorities for health and health care and the social and economic capital to address those priorities.	—
K. Other personal attributes	Other personal traits not captured elsewhere.	Tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, learning style.

Table 5. CF-PR—V. Process of Implementation

Construct	Description	Examples
A. Planning	Degree to which an implementation scheme or the methods and specific implementation steps or tasks for process redesign are developed in advance; the quality of those schemes or methods.	—
A1. Assessing (NEW)	Formal assessment of the problem or condition to be changed, including needs of users, barriers and facilitators of change.	—
A2. Goal-setting	Written goals, objectives, benchmarks, and timelines for process redesign activities and their feasibility and adequacy.	—
A3. Feedback	Procedures used to provide feedback to stakeholders and their adequacy.	—
A4. Contingency planning (NEW)	Plans for adjusting clinic or unit operations to accommodate the process redesign; plans for possible adaptation over time by laying out various scenarios and outcomes.	Adjusting patient visits and staff schedules.
B. Acquiring and allocating resources (NEW)	Resources dedicated to implementing the process redesign; the adequacy of those allocations.	—
B1. Physical space and equipment	Physical space and equipment dedicated for or impacted by the process redesign intervention.	—
B2. HIT and IT	Hardware, software, and technology dedicated to support process redesign.	—
B3. Staff time	Time dedicated to implement the PCMH intervention.	Time given to staff to attend trainings and learn PCMH techniques and strategies; and the time allowed for adjustment and adaptation.
C. Process ownership (NEW)	Directionality of leadership for the intervention (bottom-up or top-down).	—
D. Practice roles	Roles of those involved in the decision to adopt, execute, and facilitate the intervention	—
D1. Organizational leaders (NEW)	Managers and others with the authority to dedicate resources and make decisions to maintain or abandon the implementation.	—
D2. Opinion leaders	Individuals who have influence (positive or negative) on the attitudes and beliefs of their colleagues regarding the intervention.[14-16]	—
D3. Formally appointed internal implementation leaders	Individuals who have been formally appointed with responsibility for implementing the process redesign.	Project manager, team leader, project coordinator.
D4. Champions	Individuals who dedicate themselves to galvanizing and maintaining support for the process redesign and overcoming indifference or resistance.	—
D5. External change agents	Individuals outside the organization); who can facilitate or undermine decisions about process redesign adoption and implementation.	Individuals from health plans, other health care systems, policymakers.

(continued)

Table 5. CF-PR—V. Process of Implementation (continued)

Construct	Description	Comments and Examples
D6. Facilitator (NEW)	A formally appointed role that provides reflective, empathetic, and interactive counsel.	Superusers a responsible for modeling and teaching new skills and practices.[13]
D7. Frontline staff (NEW)	Administrative staff and providers (within and outside the organization) who will implement the process redesign or be impacted by it.	—
D8. Patients and other stakeholders (NEW)	Individuals and their caregivers who are impacted by the process redesign.	—
E. Engaging (	Processes involved in attracting and involving appropriate individuals in the implementation and use of the intervention.	Capitalizing on relationships between leaders and frontline staff.
F. Executing	Extent to which those involved carry out and accomplish the implementation according to plan.	—
F1. Decisionmaking (NEW)	Manner in which decisions are deliberated upon and the diversity of practice roles involved in the decisionmaking.[9]	—
F2. Staging and iteration (NEW)	Whether the implementation is carried out in incremental, iterative steps or implemented in its entirety within a specified period.	—
F3. Facilitating and coaching	Use of internal and external experts to help staff learn new processes, model best practices, and develop solutions; the structure, formality, and adequacy of these facilitative activities.	—
G. Reflecting and evaluating	Process of achieving shared understanding and participation[17] – "reflexive monitoring" and the degree to which it is attained.	Project monitoring, systematic feedback processes.

Abbreviations: HIT = health information technology; IT = information technology.

Table 6. CF-PR—VI. Measures of Implementation (New Domain)

Construct	Description	Examples
A. Acceptability (NEW)	Degree to which process redesign goals, strategies, tactics, and specific activities are agreeable, palatable, or satisfactory.	—
B. Adoption/abandonment (NEW)	Intention, initial decision, or action to employ or cease process redesign.	—
C. Appropriateness (NEW)	Intervention's degree of fit for the organization(s), discipline, provider, or consumer and/or relevance of the intervention to address specific issues or problems.	—
D. Implementation cost (NEW)	Costs of the process redesign interventions and costs associated with implementation, ongoing maintenance costs, and opportunity costs.	Investment costs for training, staffing, and IT updates.
E. Fidelity (NEW)	Degree to which process redesign was implemented as intended by those who developed and/or introduced it to the organization.	—
F. Reach (NEW)	Absolute number, proportion, and representativeness of individuals who are willing to participate in a given process redesign initiative, intervention, or program.[18]	Percentage of practices within a network that adopt open scheduling.
F1. Reach within the population (NEW)	Number of people reached, the improvement for those people reached, and the impact on the population overall.	—
F2. Reach within the organization (NEW)	Absolute number, proportion, and representativeness of individuals who are willing to participate in the intervention. [18]	Percentage of providers within a hospital that adhere to infection control protocols.
G. Penetration (NEW)	Depth of integration of a process design implementation within a service setting and its subsystems.	Among practices with e-prescribing, the percentage of patients who receive e-prescriptions.
H. Replicability (NEW)	Plans, timing, and/or method of spread within and beyond the adopting site.	—
I. Sustainability (NEW)	Extent to which changes resulting from process redesign are maintained or institutionalized within a service setting.	—
J. Evolvability (NEW)	Extent to which the change is sustained through adaptation and refinement.	—

Abbreviations: IT = information technology.

Table 7. CF-PR—VII. PR Outcomes (New Domain)

Construct	Description	Examples
A. Patient experience (NEW)	Impact on patient experiences with care including satisfaction with care and patient-provider interactions.[17]	—
B. Provider experience (NEW)	Effect(s) on a provider's burden of effort and quality of work life, communication, and interactions with patients and colleagues.[17]	—
C. Accessible (NEW)	Extent to which process redeisgn delivers access to routine/urgent care and clinical advice during and after business hours, provides electronic retrieval, allows patients to select a clinician,.[19]	—
D Quality (NEW)	Extent to which process redesign shows an on-going commitment to high quality through the use of performance measurement, evidence-based strategies, etc.[20]	—
E. Safety (NEW)	Extent to which the intervention contributes to providing safe care for patients; avoiding injuries.	—
F. Effectiveness (NEW)	Extent to which the intervention contributes to providing services to all who could benefit, without providing services to those who would not.	—
G. Timeliness (NEW)	Extent to which the intervention contributes to reducing wait times and delays, both for those who provide care and those who receive it.	—
H. .Efficiency (NEW)	Extent to which the intervention contributes to reducing waste.[5]	Reduction in equipment, supplies, provider or patient time [without harm to quality.]
I. Productivity (NEW)	Degree to which the intervention results in greater output of a service or good in the same or less amount of time.	Number of test processed per hour
J. Equitable (NEW)	Extent to which disparities in care are reduced or eradicated. [5]	—
K. Health care utilization (NEW)	Changes in the frequency, type, timing, and duration of use of health care services. [5]	—
L. Cost effects/impact (NEW)	Cost impact (summative or incremental) resulting from changes in health care utilization and efficiency. Includes fixed and variable costs.	—
M. Perceived value (NEW)	Expected and experienced improvements in better productivity, less waste.	—
N. Unintended consequences (NEW)	Emergent, interim, or longer-term outcomes that were unanticipated and usually not desired.	—

Applying the CF-PR: A Case Study

To elucidate how the CF-PR may be applied, we present below a brief case study. We note that this is an abbreviated and edited version of a longer, detailed case study prepared and published by E.L. McCarthy, "*Physician office productivity improvement through operations analysis and process redesign*."[21] RTI International and other authors of this framework document are not the authors of this case study and do not possess any copyright to this work. We use this modified example solely for illustrative purposes, to demonstrate how the CF-PR may be used.

Practice Scheduling Redesign Case Study

This is a case study of an operations improvement project at a hospital-owned physician practice structure connected with a multihospital system. The structure at these hospital-owned practices included 11 separate physician practices, with multiple physicians in each practice, and a blend of pediatrics, family, and internal medicine practices. These physician practices were very busy offices, with large patient panels, and approximately 195,000 patient encounters per year. Many of these offices were booked 3 to 5 months in advance for patient appointments. The overall focus of the analysis was on improving patient access to the practices and improving systems for faster throughput.

Project Scope

The scope of the project was comprehensive and included a step-by-step analysis of all the operational processes in each practice. Here, we focus on the following processes:

- patient appointment scheduling
- physician/patient scheduling templates
- referral process for specialist appointments
- pharmacy refills and prescriptions
- patient check-in

Each of these processes was very complex, and it was necessary to map the individual function performed at each physician office and compare the same function at other offices. A side-by-side comparison of each office's process was a major component of this analysis to identify best practices and implement changes at each office.

Improvements Identified

This analysis identified many operational improvements for each practice. Many of the opportunities focused on streamlining the system for office staff and physicians so that they could expedite patient processing more efficiently.

- **Patient appointment scheduling.** The mix of scheduled encounters among practices was standardized through "wave scheduling," which blended routine office visits, physicals, and sick visits. Wave scheduling spread the intensity of the office visits out more evenly and maximized the available time slots on the schedule and patient throughput. After the successful implementation of wave scheduling in one practice, other practices were encouraged to adopt it.

- **Physician/patient scheduling templates.** The scheduling templates for each specialty, with the same number and type of office visits scheduled in any given hour, were standardized. This change was implemented concurrent with the wave scheduling.
- **Pharmacy refills and prescriptions**. The existing manual telephone call process to communicate prescription information was replaced with a single prescription form that was faxed to each pharmacy. This form contained the prescriptions for multiple patients. The existing process relied on front desk staff or medical assistants to call each pharmacy 2 to 4 times per day to communicate prescription fill or refill information for each patient. The change to a single faxed form reduced the workload at the practices by 0.5 to 1 hour a day and increased the timeliness of prescription processing.
- **Patient check-in.** The patient check-in window is at the front of the office as patients walk in. Analysis of the check-in process at all 11 practices identified significant differences in check-in functions and processes among practices. A standard best-practice list for check-in functions was developed that included the printing of encounter forms and charts, collection of demographic and insurance information, collection of copayments, etc.

Applying the CF-PR

Below, we walk through the how-to-use flowchart detailed in Figure 3. For illustrative purposes, we examine this study at a high level with a short list of constructs. In real-world implementations, many more constructs may be relevant. Researchers will have to select a workable subset of potentially relevant constructs. This selection will likely be influenced by previous experience and research, current research aims, and practical considerations.

Step 1 – Define the intervention

In this step, the user of the framework examines the first major domain in the CF-PR: *process redesign intervention characteristics*.

- What is the intervention designed to achieve?
  The process redesign intervention strategy in this case study consists of a step-by-step analysis and operational improvement of major processes at each physician practice under consideration to improve patient access and throughput. The process redesign techniques employed include:
  (a) Mapping individual functions performed at each office, assessing their efficiency, and comparing levels of efficiency across offices;
  (b) Identifying best practices; and
  (c) Streamlining procedures to implement best practices at all offices.
  In addition, the user examines the following issues, while selecting relevant constructs from the domain.
- What are the features of the intervention?
  Here, the user considers the details of the various intervention steps mentioned above (a, b, and c), such as the steps involved in mapping the criteria for a best practice, and methods for streamlining. Relevant constructs that may be used include *feasibility, trialability*, and *complexity*. See Table 1 for definitions of constructs.
- Who is the intended target group?
  Relevant constructs that may be used include *targeted groups* and *workflows and dependencies*. See Table 1.

Step 2 – Define the outer setting

- What components of the environment will impact the implementation?
  These may include political context, social context, economic context, etc. Here, the user examines various relevant outer setting constructs that may include, for example, *external pressure* (e.g., from competing hospital systems that have successfully implemented similar process redesign interventions), and *technological environment* (e.g., new software that facilitates faster processing of patients at check-in). See Table 2.

Step 3 – Define the inner setting

- What components of structure and process within the inner setting will impact the implementation?
  These may be tangible and intangible manifestations of structural characteristics, networks and communications, culture, climate, readiness, etc. Relevant constructs here include *culture* (e.g., how will staff adapt to changing longstanding pharmacy refill processes and will there be significant push-back from staff?) and *knowledge* (e.g. knowledge gained by involved staff who have experience with similar interventions in the past). See Table 3.

Step 4 – Define the characteristics of the individuals/teams involved

- What are the characteristics of individuals (or teams) that will help in making the process redesign intervention and/or implementation successful?
  A relevant construct may include *skills and competences* (e.g., do staff members have the skills needed to effectively conduct wave scheduling or do they require additional training?). See Table 4.

Step 5 – Define the processes required to achieve desired level of use

- What are the implementation processes that are required to achieve individual- and organizational-level use of the intervention?
  Relevant constructs to consider may include *planning* (e.g., does the roll-out have clear milestones, timelines, and dedicated staff accountable for actions?) and *staging and iteration* (e.g., are changes being introduced slowly and refined in one site before scaling to another site or are the changes being implemented across the board with each site responsible for adapting to local conditions?). See Table 5.

Step 6 – Define successful implementation

- What are the attributes of the implementation process that demonstrate it was carried out well and can be replicated, scaled, and sustained?
  Constructs here include *acceptability* (e.g., do staff members believe that the goals of the intervention are acceptable?), *implementation cost* (e.g., what are the financial costs of the implementation and how long will it take to see a return on investment?), *reach* (percentage of offices that use wave scheduling 6 months after implementation) and *penetration* (proportion of staff within each practice using the wave scheduling). See Table 6.

Step 7 – Define the outcomes

- What are the specific, measurable outcomes that will result from the intervention? Relevant constructs, representing outcomes, may be *accessibility, patient experience, provider experience, timeliness,* and *efficiency*. The user is encouraged to revisit previous domains to ensure that the outcomes selected in this step are supported by the intervention. In particular, the user would tie these outcomes back to the goals of the intervention (improving patient access and throughput) listed under the first step. See Table 7.

Note: Constructs in the CF-PR, because they represent the components of a complex system intervention, can be explored at multiple levels (i.e., at the individual, team, or organization level). In Table 8, we show how a handful of constructs applicable to this case study are relevant across multiple organizational levels. For brevity, we show only three levels, but other levels may be relevant depending on the scenario. For example, in some cases, a "unit" might be a level that comprises groups of "teams." However the levels may be defined, the important aspect is to ensure that users of the framework appreciate that each construct may (and in most cases should) be applied at various levels, and not just at one.

Table 8. Example of application of constructs to diverse levels of analysis by organizational level

Construct	Individual	Team	Organization
External pressure	—	—	✓
Workflows	—	✓	✓
Planning	—	✓	✓
Accessibility	✓	—	—

Contextual Framework for Patient-Centered Medical Home Interventions

Overview

A Patient-Centered Medical Home (PCMH), as defined by the Agency for Healthcare Research and Quality (AHRQ), is an organizational model of primary care with the following functions and attributes: comprehensive, patient-centered, coordinated, accessible, quality, and safety. Achieving these functions and attributes requires a complex set of changes and innovations that go well beyond the boundaries of the practice setting and includes provider and hospital networks, insurers, and federal agencies. Examples of PCMH interventions within the practice setting would include team-based care, the use of facilitation and coaching to develop skills, and disease registries that allow the provider to see patients not just as individuals but as part of a larger population with common needs and concerns.

The purpose of the Contextual Framework for Patient-Centered Medical Homes (CF-PCMH) is to guide research and evaluation of PCMH implementation within a broad range of organizational settings. The primary users for this framework are investigators and practitioners who wish to understand why PCMH implementation succeeds or fails and whether the PCMH intervention or its components can be replicated and scaled to other settings. The CF-PCMH is intended to guide users in the design of a study or evaluation project. Some practitioners, because of the comprehensiveness of the CF-PCMH, may also find it useful for intervention design and continuous quality improvement. Investigators can apply the CF-PCMH to a whole intervention with various distinct parts or to one or more those parts.

The CF-PCMH was modified using the feedback obtained from a literature scan, consultation with the original Consolidated Framework for Implementation Research (CFIR) team and experts familiar with that work, and two separate Technical Expert Panels (TEPs) that examined the framework objectively during a series of calls. The CF-PCMH reflects these various sources of input.

This chapter is organized into six sections. The Organization of the CF-PCMH section briefly describes the domains of the CF-PCMH. Modifications to the CF-PCMH describes the notable changes made to the CFIR for PCMH. The CF-PCMH is presented in two forms: a graphic followed by a full explication of the domains, constructs, and subconstructs in Tables 9 through 15. The How to Use the CF-PCMH section gives users a step-by-step roadmap for approaching the multiple and complex dimensions of the CF-PCMH. This chapter concludes with a case study of a PCMH implementation that applies the CF-PCMH using the how-to steps presented in the roadmap.

Organization of the CF-PCMH

Tables 9 through 15 show the CF-PCMH. Factors are organized into six domains and further subdivided into precise categories of constructs and subconstructs. Constructs labeled "new" were not part of the original CFIR. The CF-PCMH domains,[1] summarized with their respective constructs and definitions in the first two columns of Tables 9 through 15, include:

- **PCMH Intervention Characteristics:** The characteristics of the intervention being implemented into a particular organization, including core components (the essential and indispensable elements of the intervention itself) and an adaptable periphery (adaptable

elements, structures, and systems related to the intervention and organization into which it is being implemented).

- **Outer Setting**: Includes the economic, political, and social context within which an organization resides.
- **Inner Setting:** Tangible and intangible manifestation of characteristics of the organizations involved in the intervention, including structural characteristics, networks and communications, culture, climate, and readiness that all interrelate and influence implementation.
- **Characteristics of Individuals and Teams**: The individuals (as carriers of cultural, organizational, professional, and individual mindsets, norms, interests, and affiliations) involved with the intervention and/or implementation process. Includes patients and caregivers.
- **Process of Implementation**: As used here, this term refers to the course of *actions* (e.g., planning, engaging, and reflecting) to achieve individual- and organizational-level use of the intervention, as designed.
- **Measures of Implementation**: These elements refer to what Proctor et al.[6] call "implementation outcomes"; they are intermediary outcomes that describe how well the implementation was carried out and prospects for sustainability.
- **PCMH Outcomes**: The results of the PCMH implementation, defined as the targets of the PCMH intervention.

The top-tier domains (presented above) represent families of constructs, and these are subdivided into more precise categories of subconstructs. Users of the framework may find it helpful to refine these subconstructs even further for specific research purposes. Researchers could use these frameworks to define and review the range of potentially relevant concepts and variables as they prepare an implementation study. Additionally, they may engage in prestudy to determine which constructs are likely to be most useful. During their research, they may refine their selection of constructs and their specifications of them in response to data that emerge from the field or in response to changes in the intervention process and context that take place during the life course of the intervention.

Modifications in the CF-PCMH

The CFIR served as the foundation from which the CF-PCMH (as well as the adapted framework for process redesign, the CF-PR) was developed. In addition, the CF-PR and CF-PCMH were developed simultaneously, and therefore additions to one framework resulted in similar additions to the other when appropriate. Below, we briefly list the constructs, by domain, that are new for the CF-PCMH (i.e., were not present in the original CFIR or in the CF-PR). For definitions of these constructs, we direct the reader to the CF-PCMH tables, which begin with Table 9.

- Intervention Characteristics: The CF-PCMH added *practice centeredness* to describe the extent to which a practice could carry out the PCMH intervention on its own versus relying on external service providers who may be brought in to provide specific services related to the intervention. Also added were *history* with the intervention and the *location of PCMH activities*.
- Outer Setting: The CF-PCMH includes a few new constructs related to features of the inner setting that may impact the PCMH evaluation, particularly focused on the patient

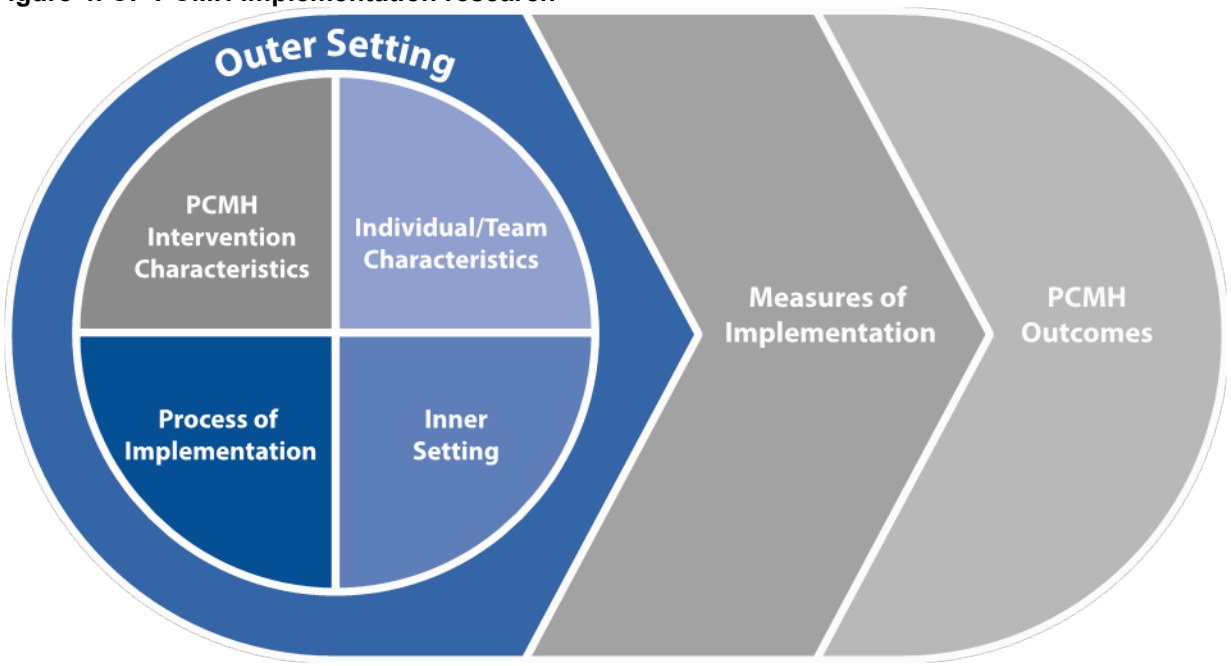
health profile, patient needs, and caregiver needs. These are *population needs and resources* in which the practice serves*, the patient needs and resources* of those in the practice *as well as caregiver need and resources,* and *community resources* available within the practice service area.

- Inner Setting: *Patient centeredness* was added to capture the degree to which the practice is aware of patient needs and seeks to addresses them. *Patient self-management infrastructure* is also a new construct, included to capture resources made available to patients in the PCMH. The construct *human factors* was renamed *HIT/IT accessibility* to better resonate with PCMH users.
- Characteristics of Individuals and Teams: A new construct, *sociodemographic characteristics*, provides a place for users to capture important socioeconomic and demographic information of patient groups. *Role, authority,* and *collective efficacy* were added as elements important to teaming and collaboration.
- Process: The CF-PCMH added numerous constructs and subcontracts to the Process domain. These included the need to add *assessing* to cover activities designed to identity needs and barriers, *contingency planning* for unexpected events, and *acquiring and allocating new resources.* To practice roles we added *organizational leaders, frontline staff, facilitators,* and *patients and stakeholders* to better articulate the focus on patients. Under execution, we added *decisionmaking*.
- Measures of Implementation: This is a new domain. The CF-PCMH does not contain any new constructs in this domain in addition to those described in *Modifications in the CF-PR*.
- PCMH Outcomes: This is a new domain. The CF-PCMH added a number of PCMH-specific outcomes in addition to a number already described in *Modifications in the CF-PR*. These outcomes include *patient experience, provider experience, process of care* (further subdivided by six subconstructs), and *clinical outcomes.*

Graphic Representation of the CF-PCMH

Figure 4 is a graphic representation of the CF-PCMH. It shows the relationships of five of the domains to measures of implementation success and various PCMH outcomes. On the left side of the figure, the five domains are shown in a circle. The inner part of the circle is divided into four sections, representing each of the following domains: PCMH Intervention Characteristics, Individual/Team Characteristics, Inner Setting, and Process of Implementation. The outer ring encircles the inner ring, and represents the Outer Setting. The five domains flow into the measures of implementation success, which in turn affects the PCMH outcomes.

Figure 4. CF-PCMH implementation research



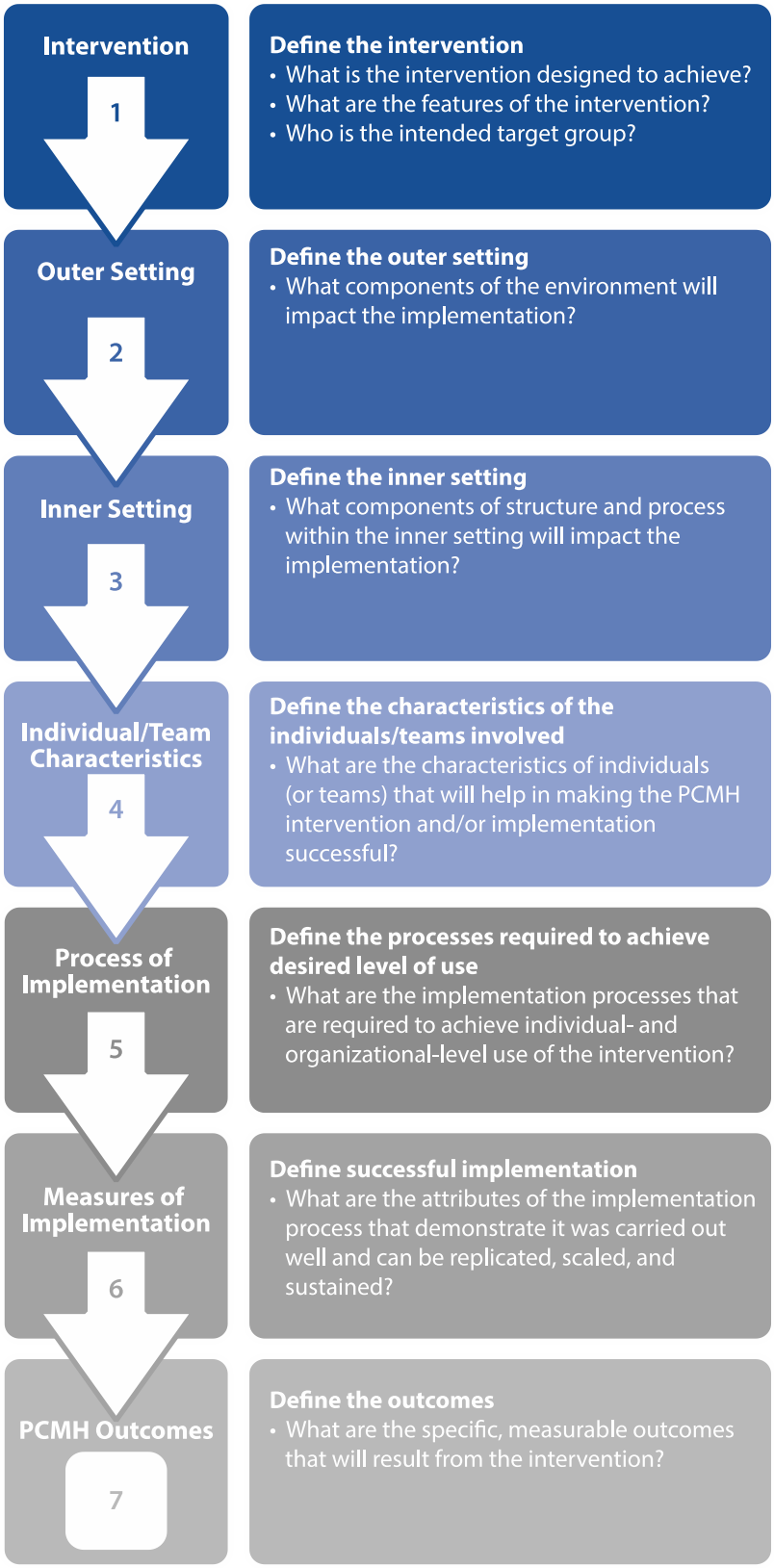
Abbreviations: PCMH = Patient-Centered Medical Home.

How to Use the CF-PCMH

The evolving nature of PCMH interventions, and the heterogeneity of the settings in which the PCMH model may be applied, is such that the details of implementation will vary from one setting to another. Therefore, the CF-PCMH does not prescribe a set of normative constructs that must be considered; rather, it provides a large set of potential constructs within major domains, from which investigators can choose those constructs relevant to their particular intervention and research goals.

The flowchart in Figure 5 presents step-by-step guidance on how this framework may be used. The flowchart presents a series of questions, and each series is tied to a particular domain in the framework (Tables 9 through 15). As these questions are considered, the user should refer to the appropriate domain in the framework table to see which constructs are relevant. For example, Step 1 corresponds to the intervention domain, and as users consider the various issues related to this domain, they should refer to the framework to choose those constructs relevant to them. As mentioned previously, the framework does not prescribe which constructs must be selected due to the diversity of research objectives and to variations between different PCMH interventions. While following this step-by-step process of using the framework, we recommend that users of the framework select qualities, features, or characteristics that are closely tied to intervention outcomes.

Figure 5. How to use the CF-PCMH



Abbreviations: CF-PCMH = Contextual Framework for Patient-Centered Medical Home; PCMH = Patient-Centered Medical Home.

The CF-PCMH

Here we present the CF-PCMH in Tables 9 through 15 with brief definitions of the constructs and subconstructs, and examples. Constructs labeled "new" are additions to the original CFIR.[1] Based on TEP input we added clarifying examples and comments for those constructs and subcontracts that were unclear or complex. Each construct or subconstruct is independent and should be applied as appropriate to the research questions and objectives.

Table 9. CF-PCMH—I. PCMH Intervention Characteristics

Construct	Description	Examples
A. Vision and change strategy (NEW)	Proposed changes envisioned by the PCMH and the theory of change: how the PCMH strategy is supposed to work, what it is meant to achieve/do, and how it is to be executed and articulated in logic models, stated goals, objectives, and performance measures.	—
B. Targeted groups	Practice staff, patients, caregivers, and others who are the intended recipients or beneficiaries of PCMH.	—
C. Intervention source	Identifying who (which individuals or groups) originated the PCMH initiative, and/or from which source the components of the initiative were derived.	—
D. Evidence strength and quality	Target group and other stakeholders' perceptions of the quality and validity of evidence supporting the belief that the PCMH will have the desired outcomes.	Standards and recommendations from the National Committee for Quality Assurance
E. Relative advantage	Target group and other stakeholders' perception of the advantage of implementing PCMH instead of other possible interventions.	—
F. Feasibility (NEW)	Target group and other stakeholders' perception of the extent to which the PCMH can be successfully used or carried out within a given organization or setting.	—
G. Adaptability	Target group and stakeholders' perception of the degree to which PCMH strategies, techniques, and practices can be adapted, tailored, refined, or reinvented to meet local needs. Capacity to change course (undo or change implementation) if warranted.	—
H. Trialability	Target group and stakeholders' perception of the ability to test components of the PCMH on a small scale in the practice or organization, and to be able to reverse course (undo implementation) if warranted.	—
I. Complexity	Target group and stakeholders' perception of the difficulty of implementation, reflected by duration, scope, centrality, and intricacy and number of steps required to implement.	—
J. Compatibility (NEW)	Target group and stakeholders' perception of the alignment of the meaning, values, and norms attached to PCMH with those held by members of the practice or organization.	—

(continued)

Table 9. CF-PCMH—I. Characteristics of the PCMH Intervention (continued)

Construct	Description	Examples
K. Radicalness (NEW)	Target group and stakeholders' perception of the degree of difference between the change envisioned and the current state. The degree of disruption to the current state required.[7]	—
L. User control (NEW)	Degree to which the practice can implement PCMH on its own vs. reliance on external consultants.	—
M. Location of intervention (NEW)	External services, supplemental providers, or new provider roles used to carry out the PCMH intervention.	
N. Workflows (NEW)	Office tasks and workflows, including interdependences between them, that will be intentionally redesigned or impacted by the PCMH transformation.	—
O. Task/process standardization (NEW)	Degree to which the PCMH seeks to standardize selected tasks and/or processes that require iterative consultation.	—
P. History (NEW)	Experiences of similar interventions within the setting and within the target population.	Patients' experience with a patient navigator prior to PCMH.

Abbreviations: PCMH = Patient-Centered Medical Home.

Table 10. CF-PCMH—II. Outer Setting

Construct	Description	Examples
A. External networks	Practice's involvement with networks and partnerships that support the transition to PCMH and are involved in similar efforts.	Improvement collaborative.
B. External pressure	Pressure emanating from outside the organization to implement a PCMH intervention.	Key peer or competing organizations have already implemented PCMH; there is competitive pressure to secure a better share of the market.
C. External policy incentives	Policies and regulations (government or other central entity), external mandates, recommendations and guidelines, and payment schemes that promote or undermine the adoption of PCMH.	CMS incentive payments for meaningful use of electronic health records.
D. Technological environment (NEW)	Technological trends and movements and the availability of technological innovations that may affect the intervention and its context.	Health information exchanges.
E. Population needs and resources (NEW)	Prevalence of conditions and disease in the population served and the characteristics of the community that are determinants of health status.	Environmental quality, poverty, transportation, employment, health determinants.
F. Community resources (NEW)	Availability and access to service providers, aging resources, and multiple levels of community services and supports not directly a part of the PCMH.	—

Abbreviations: PCMH = Patient-Centered Medical Home.

Table 11. CF-PCMH—III. Inner Setting

Construct	Description	Examples
A. Structural characteristics	Social architecture; age; maturity; size; composition of the team, unit, organization, or system; and the patient panel served.	Staffing mix, clinician demographics, clinician training, employment status of physicians.
B. Team and network characteristics	Influence, breadth, role diversity, depth, teams, networks of teams, and communication practices and protocols within and between teams. [9]	A team's capacity for self-organization.
C. Culture	Norms, values, and beliefs within a team, unit, or practice that affect views of PCMH and its implementation.	—
D. Implementation climate	Capacity or reserve[10] for change and the shared receptivity of involved individuals to the intervention.	—
D1. Tension for change	Degree to which stakeholders perceive the current situation as intolerable or needing change.	—
D2. Mandate	Whether compliance with the PCMH initiative is expected.	—
D3. Accountability	Whether entities are subject to tangible consequences for noncompliance.	—
D4. Relative priority	Individuals' shared perception of the importance of the PCMH implementation within the organization.	—
D5. Organizational incentives	Extrinsic incentives and rewards offered to adopt PCMH.	Shared savings, promotions, increased stature, or respect.
D6. Learning climate	Organization's willingness to promote trial and error, test new methods, and innovate.	—
E. Readiness for implementation	Tangible and immediate indicators of organizational commitment to its decision to implement PCMH.	—
E1. Leadership commitment	Degree of commitment, involvement, and accountability of leaders and managers to quality and safety improvement in general, and to the PCMH initiative specifically.	—
E2. Staff commitment (NEW)	Degree of commitment, involvement, and accountability of physicians, nurses, and other staff to quality and safety improvement in general, and to the PCMH initiative specifically.	—
F. Information Access	Ease of access for practice staff to digestible, applicable information and knowledge about PCMH and its transmission through training and education.	—
G. IT and HIT resources (NEW)	Technological infrastructure in place to support electronic information management and the redesign of patient care.	—
G1. HIT systems	Electronic information management infrastructure and technologies available to clinicians to manage patient care, data, and communications.	Decision support tools, e-prescribing, electronic health records.
G2. IT systems	Technological systems and capabilities to support PCMH.	Hardware, software, server space, bandwidth, interoperability, health information exchange.

(continued)

Table 11. CF-PCMH—III. Inner Setting (continued)

Construct	Description	Examples
G3. HIT/IT accessibility (NEW)	Includes features of the physical, technical, and social environment in the practice that determine the use, accessibility, and acceptability of technology in patient care.[11]	—
H. Measurement capability and data availability (NEW)	Availability or ability to obtain or calculate necessary data across organizations. Issues include measurement differences between organizations; sharing; accountability for collection, documentation, and analysis; and timeliness.	—
I. Training and education (NEW)	General level of resources dedicated to training and education available within the organization.	Access to online training tools, time provided for training and education, funding for training.
J. Other resources (NEW)	Resources for implementation and ongoing operations to support change and innovation.	Money, physical space, equipment, staff time.
K. Patient self-management infrastructure (NEW)	Training, counseling, and education available to patients prior to PCMH to manage their condition in both hospital and ambulatory settings and through other organizations post-discharge, or resources that cross organizations.	—
L. Continuity (NEW)	Information continuity (exchange of information) and relationship continuity, both with provider and patients/caregivers and across organizations.	—
M. Patient centeredness (NEW)	Extent to which patient needs are known and prioritized by the practice prior to PCMH. The resources and services in place to meet those patient needs.	Patient needs assessments, patient portals, mobile health applications.

Abbreviations: HIT = health information technology; IT = information technology; PCMH = Patient-Centered Medical Home; QI = quality improvement.

Table 12. CF-PCMH—IV. Characteristics of Individuals and Teams

Construct	Description	Examples
A. Knowledge and beliefs	Attitudes toward and value placed on the PCMH as well as their familiarity with facts, truths, and principles related to the intervention.	—
B. Skills and competencies (NEW)	Degree of relevant subject matter expertise, skills, and competencies within the implementing team, unit, and organization. The gap between the current state and the skills and competencies needed to implement PCMH successfully.	—
C. Role (NEW)	Individual's or team's role and responsibility and extent of multiple or shared roles.	—
D. Authority (NEW)	Perceived and actual degree of authority to make decisions and act autonomously.[12]	—
E. Self-efficacy	Belief and confidence in their capacity to execute the courses of action necessary to achieve PCMH goals.	Patient confidence in accessing and using a patient portal.
F. Collective efficacy (NEW)	Belief and conviction of individuals and teams involved that the PCMH transformation can be carried out in cooperation with others.[13]	—
G. Stage of change	Characterization of the phase an individual or team is in, as he or she progresses toward skilled, enthusiastic, and sustained application of PCMH strategies.	—
H. Identification with organization	How individuals or teams perceive the organization and their relationship and degree of commitment with that organization.	—
I. Socioeconomic demographics (NEW)	Characteristics related to the individual's socioeconomic status.	—
J. Patient needs and resources	Patient priorities for health and health care and the social and economic capital to address those priorities.	—
K. Caregiver needs and resources (NEW)	Caregiver priorities for health and health care and the social and economic capital to address those priorities.	—
L. Other personal attributes	Other personal traits not captured elsewhere.	Tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, learning style.

Abbreviations: PCMH = Patient-Centered Medical Home.

Table 13. CF-PCMH—V. Process of Implementation

Construct	Description	Examples
A. Planning	Degree to which an implementation scheme or the methods and specific implementation steps or tasks for PCMH are developed in advance; the quality of those schemes or methods.	—
A1. Assessing (NEW)	Formal assessment of the problem or condition to be changed including barriers and facilitators to change.	—
A2. Goal-setting	Written goals, objectives, benchmarks, and timelines for PCMH activities and their feasibility and their adequacy.	—
A3. Feedback	Procedures used to provide feedback to stakeholders and their adequacy.	—
A3. Contingency planning (NEW)	Plans for adjusting staff schedules and patient loads, increasing the availability of resources to meet the demands of implementation, plans for possible adaptation over time by laying out various scenarios and outcomes.	—
B. Acquiring and allocating resources (NEW)	Resources dedicated to implementing the PCMH intervention; the adequacy of those allocations.	—
B1. Training and education	Training and education to implement PCMH.	—
B2. Physical space and equipment	Physical space and equipment dedicated for or impacted by the PCMH intervention.	—
B3. HIT and IT	Hardware, software, and technology acquired and dedicated to support PCMH, and their adequacy.	Patient portals, disease registries, mobile applications.
B4. Staff time	Time dedicated to implement the PCMH intervention.	Time given to staff to attend trainings and learn PCMH techniques and strategies; and the time allowed for adjustment and adaptation.
C. Process ownership (NEW)	Directionality of leadership (bottom-up or top-down).	—
D. Practice roles	Roles of individuals involved in the decision to adopt, execute, and facilitate PCMH.	—
D1. Organizational leaders (NEW)	Managers and others with the authority to dedicate resources and make decisions to adopt, maintain or abandon the implementation.	—
D2. Opinion leaders	Individuals who have influence (positive or negative) on the attitudes and beliefs of their colleagues regarding the intervention.[14,16] Opinion leaders include experts and peers.[15]	—
D3. Formally appointed internal implementation leaders	Individuals who have been formally appointed with responsibility for implementing an intervention.	Coordinator, project manager, team leader.
D4. Champions	Individuals who dedicate themselves to galvanizing and maintaining support for PCMH and overcoming indifference or resistance t.	—
D5. External change agents	Individuals outside the organization who can facilitate or undermine decisions about PCMH adoption and implementation.	Health plans, other health care systems, policymakers.

(continued)

Table 13. CF-PCMH—V. Process of Implementation (continued)

Construct	Description	Examples
D6. Facilitator (NEW)	Formally appointed role that provides reflective, empathetic, and interactive counsel.	Superusers responsible for modeling and teaching new skills and practices.[13]
D7. Frontline staff (NEW)	Administrative staff and providers (within and outside the organization) who will implement the PCMH or be impacted by it.	—
D8. Patients and other stakeholders (NEW)	Patients and other stakeholders impacted by the PCMH.	Family members, advocates, and social service providers
E. Engaging	Processes involved in attracting and involving appropriate individuals in the implementation and use of the intervention.	Social marketing, various outreach activities.
E1. Engaging relationships between organizations, external context (NEW)	Engaging, coordinating, crossing boundaries, and developing or capitalizing on relationships to providers, leaders, and frontline staff in organizations involved in the intervention, as well as the external context (other providers, resources, funders).	—
F. Executing	Extent to which those involved carry out and accomplish the implementation according to plan.	—
F1. Decisionmaking (NEW)	Manner in which decisions are deliberated upon and the diversity of practice roles involved in the decisionmaking.[9]	—
F2. Staging and iteration (NEW)	Degree to which the PCMH implementation is carried out in iterative, incremental steps or implemented in its entirety within a specified period.	—
F3. Facilitating and coaching	Use of internal and external experts to help staff learn new processes, model best practices, and develop solutions; the structure, formality, and adequacy of these facilitative activities.	—
G. Reflecting and evaluating	Process of achieving shared understanding and participation[17]—"reflexive monitoring" and the degree to which it is attained.	Project monitoring, systematic feedback processes.

Abbreviations: HIT = health information technology; IT = information technology; PCMH = Patient-Centered Medical Home.

Table 14. CF-PCMH—VI. Measures of Implementation (New Domain)

Construct	Description	Examples
A. Acceptability (NEW)	Degree to which PCMH goals, strategies, tactics, and specific activities are agreeable, palatable, or satisfactory.	—
B. Adoption/abandonment (NEW)	Intention, initial decision, or action to try to employ or cease PCMH.	—
C. Appropriateness (NEW)	Intervention's degree of fit for the organization(s), discipline, provider, or consumer and/or relevance of the intervention to address specific issues or problems.	—
D. Implementation cost (NEW)	Costs of the PCMH interventions and costs associated with implementation, including investment (, ongoing maintenance costs, and opportunity costs.	Training, staffing, IT updates
E. Fidelity (NEW)	Degree to which PCMH was implemented as intended by those who developed and/or introduced it to the practice.	—
F. Reach (NEW)	Absolute number, proportion, and representativeness of individuals who are willing to participate in a given PCMH initiative, intervention, or program.[18]	Percentage of practices within a network that provide e-mail consultations.
F1. Reach within the population (NEW)	Number of people reached, the improvement for those people reached, and the impact on the population overall.	—
F2. Reach within the organization (NEW)	Absolute number, proportion, and representativeness of individuals who are willing to participate in the intervention, including different disciplines, units, and organizations.[18]	—
G. Penetration (NEW)	Depth of integration of a PCMH implementation within a service setting and its subsystems.	Among providers who have e-prescribing, the percentage of patients who receive e-prescriptions.
H. Replicability (NEW)	Plans, timing, and/or method of spread (how PCMH is spread within and beyond the adopting practice sites).	—
I. Sustainability (NEW)	Extent to which changes resulting from PCMH are maintained or institutionalized within a practice's ongoing, stable operations; the degree to which PCMH becomes part of a continuous learning and improvement process within the practice.	—
J. Evolvability (NEW)	Extent to which the change is capable of being sustained through adaptation and refinement.	—

Abbreviations: IT = information technology; PCMH = Patient-Centered Medical Home.

Table 15. CF-PCMH—VII. PCMH Outcomes (New Domain)

Construct	Description	Examples
.A Patient and caregiver-centered outcomes (NEW)	Patient and caregiver defined goals and care consistent with patient and Patient caregiver preferences	Patient and caregiver would rather be seen by a physician rather than a nurse practitioner.
B. Patient/caregiver experience (NEW)	Impact of PCMH on patient and caregiver experiences with care including satisfaction with care and patient-provider interactions.[17]	—
C. Provider experience (NEW)	Effect(s) of PCMH on a provider's burden of effort and quality of work life, communication, and interactions with patients and colleagues.[17]	—
D. Process of care (NEW)	Key measurable processes of Care Transitions interventions.[20]	—
D1. Patient-centered (NEW)	Extent to which PCMH provides enhanced access to and continuity of care, collaborates with patients and family to develop and manage care plans, provides resources to support self-care, and is engaged in performance improvement.[19]	—
D2. Coordinated (NEW)	Extent to which PCMH tracks, follows up on, and coordinates tests, referrals and care at other facilities; extent to which the practice follows up with discharged patients. [19]	—
D3. Comprehensive (NEW)	Extent to which PCMH is responsible for satisfying all the medical needs of a patient, including prevention and specialty care.[20]	—
D4. Accessible (NEW)	Extent to which PCMH delivers routine/urgent care and clinical advice during and after business hours, provides electronic access, allows patients to select a clinician, and is focused on team-based care with trained staff.[19]	—
D5. Quality (NEW)	Extent to which PCMH shows an on-going commitment to high quality through the use of performance measurement, evidence-based strategies, etc.[20]	—
D6. Safety (NEW)	Extent to which PCMH collects and uses safety data, and shares such data publicly as a marker of ongoing commitment to safety and quality.[20]	—
E. Effectiveness (NEW)	Extent to which the intervention contributes to providing services to all who could benefit, without providing services to those who would not	—
F. Timeliness (NEW)	Extent to which the intervention contributes to reducing wait times and delays, both for those who provide care and those who receive it.	—
G. Clinical outcomes (NEW)	Result of a medical intervention as captured by changes in health status.	—
H. Health care utilization (NEW)	Changes in the frequency, type, timing, and duration of health care services due to PCMH.	—
I. Cost effects/impact (NEW)	Cost impact of a PCMH implementation effort (summative or incremental) resulting from changes in health care utilization and efficiency. Includes fixed and variable costs.	—
J. Perceived value (NEW)	Expected and experienced improvements in better health care, improved quality of work life.	—
K. Unintended consequences (NEW)	Emergent, interim, or longer-term outcomes that were unanticipated and usually not desired.	Staff burnout from burden of balancing "day job" with PCMH activities.

Abbreviations: PCMH = Patient-Centered Medical Home..

Applying the CF-PCMH: A Case Study

To elucidate how the CF-PCMH may be applied, we present below a brief case study. We note that this is an abbreviated, modified, and edited version of a longer, detailed manuscript prepared by Driscoll et al., "Process and outcomes of patient centered medical care with Alaska native people at Southcentral Foundation."[23] RTI International and other authors of this framework document are not the authors of the original manuscript and do not possess any copyright to this work. We have adapted the manuscript to use as an example of how the CF-PCMH may be used. While significant portions of this case study are presented verbatim from the original manuscript, we have also made various modifications to the text, including shortening the study and focusing on specific outcomes for illustrative purposes.

Alaska Southcentral Foundation Case Study

The Southcentral Foundation (SCF) is an Alaska Native–owned, nonprofit organization serving nearly 60,000 Alaska Native and American Indian people living in south-central Alaska with the mission "to work with the Native Community to achieve wellness through health and related services." In 1997, Alaska Native and American Indian residents of south-central Alaska began receiving care at new hospital and outpatient facilities at the Alaska Native Medical Center (ANMC). Soon after, the SCF assumed responsibility for primary care services at ANMC after more than 50 years of management by the Indian Health Service (IHS).

After assuming responsibility for primary care services, the SCF leadership began implementing key components of the PCMH model. The tailored model is based on several key characteristics of a PCMH. These are described below:

- Team-based care: Coordinated care is delivered by multidisciplinary teams rather than by individual clinicians. These teams include primary care physicians or physician assistants, nurses, certified medical assistants, and other clinicians. Over time, behavioral health consultants, nutritionists, and appointment schedulers were added.
- Empanelment: Patients are matched, either by self-selection or assignment, to an integrated and comprehensive care team. Patients schedule primary care appointments with their team members.
- Open access: To the extent possible, patients' barriers to access are mitigated through open scheduling, expanded office hours, and increased availability of electronic communication between patients and team members.

In the remainder of the case study, we will use this example to demonstrate how the CF-PCMH may be used to evaluate this intervention.

Applying the CF-PCMH

Below, we walk through the how-to-use flowchart detailed in Figure 5. For illustrative purposes we have used a brief case study and examine this study at a high level. In real-world implementations, the level of detail will be significantly greater. For each step, we have selected a few constructs as examples.

Step 1—Define the intervention.

In this step, the user of the framework examines the first major domain in the CF-PCMH: *Characteristics of the PCMH Intervention*.

- What is the intervention designed to achieve?
  The goal of the PCMH intervention is to improve access to and coordination of care among patients served by SCF's primary care services.
- What are the features of the intervention?
  Here, the user considers the details of the various intervention components specified above, which includes three main components: empanelment, open access, and team-based care. In this case, we address all three, but another option is to limit the focus to only one of these components. The user may consider *evidence strength and quality* as a potential construct to include (e.g., among key stakeholders at SCF, what are the perceptions of the quality and validity of the three components selected; are there existing standards and/or publications that can provide supporting evidence?)
- Who is the intended target group?
  Relevant constructs that may be used include *targeted groups* and *workflows*. See Table 9.

Step 2—Define the outer setting

- What components of the environment will impact the implementation?
  These may include political context, social context (including native American subculture[s]), economic context, and *population needs and resourc*es (e.g., what are the specific health needs, if any, of the local Alaskan population and how will the PCMH intervention ensure that these needs are well-served?). See Table 10.

Step 3—Define the inner setting

- What components of structure and process within the inner setting will impact the implementation?
  These may be networks and communications, culture, climate, readiness, etc. Relevant constructs here include *structural characteristics* (e.g., how many physicians are employed by the SCF; in how many buildings are services provided) and provider *culture* (e.g., how will staff adapt to the concept of team-based care, which will include more frequent communication and coordination between individuals; how comfortable are physicians with increased communications and how can the transitions be made smoother?). See Table 11.

Step 4—Define the characteristics of the individuals/teams involved

- What are the characteristics of individuals (or teams) that will help in making the PCMH intervention and/or implementation successful?
  Here, the user could examine *patient needs and resources* (e.g., are patients able to schedule appointments during various hours when they need to do so? Can they make appointments on-line or by email?). Other relevant constructs here include *skills and competences* (e.g., do staff members have the skills needed to successfully form integrated and comprehensive care teams; do staff members require training?), *role* (who is responsible for which tasks under the new team-based care?) and *authority* (if there are

multiple physicians involved in care for a patient, which physicians will have override authority?). See Table 12.

Step 5—Define the processes required to achieve desired level of use

- What are the implementation processes that are required to achieve individual- and organizational-level use of the intervention?
  Relevant constructs to consider may include *planning* (e.g., does the PCMH intervention have clear milestones, timelines, and dedicated staff accountable for actions?) and *staff time* (e.g., are staff given sufficient time to implement various changes, while not compromising the various functions they are currently responsible for?). See Table 13.

Step 6—Define measures of implementation

- What are the attributes of the implementation process that demonstrate it was carried out well and can be replicated, scaled, and sustained?
  Relevant constructs here may include *acceptability* (e.g., the degree to which stakeholders find SCF's PCMH implementation agreeable and satisfactory), *cost* (e.g., the total cost of implementing the three components of PCMH, and whether this stays within a set budget), and *reach within organization* (e.g., the number of units within SCF where empanelment is functioning as expected 6 months after completion of intervention). See Table 14.

Step 7— Define the outcomes

- What are the specific, measurable outcomes that will result from the intervention?
  Relevant constructs, representing outcomes, may include *process of care* (e.g., is the SCF able to provided care that satisfies relevant defining attributes of PCMH, such as being *coordinated*, *accessible,* and *patient-centered?*). The user is encouraged to revisit previous domains to ensure that the outcomes selected in this step are logically supported by the intervention. In particular, the user would tie these outcomes back to the goals of the intervention (improving access and coordination of care) listed under the first step. See Table 15.

Note: The constructs in the CF-PCMH, because they represent components of a complex system intervention, can be explored at multiple levels (i.e., at the individual, team, or organization level) as shown in Table 16 below. The number of levels, and their definitions, will vary based on the specific scenario. In Table 16, we show how a handful of constructs applicable to this case study are relevant across multiple organizational levels. For brevity, we show only three levels, but other levels may be relevant depending on the scenario. For example, in some cases, a "unit" might be a level composed of groups of "teams." However the levels may be defined, the important aspect is to ensure that users of the framework appreciate that each construct may (and in most cases should) be applied at various levels, and not just at one.

Table 16. Example of application of constructs to diverse levels of analysis by organizational level

Construct	Individual	Team	Organization
Evidence strength and quality	✓	—	—
Population needs and resources	—	—	✓
Culture	✓	✓	✓
Process of care	✓	✓	✓

Contextual Framework for Care Transitions Interventions

Overview

Care Transitions can be defined as "the movement patients make between health care practitioners and settings as their condition and care needs change during the course of a chronic or acute illness."[24] Interventions to improve transitions, or *Transitional Care*, are "a set of actions designed to ensure the coordination and continuity of health care as patients transfer between different locations or different levels of care within the same location."[25]

The Contextual Framework for Care Transitions (CF-CT) presented here builds on previous adaptations of the Consolidated Framework for Implementation Research (CFIR)[1] for process redesign for efficiency and cost reduction (CF-PR) and Patient Centered Medical Homes (CF-PCMH). The purpose of the framework is to guide research and evaluation of Care Transitions implementation within a broad range of organizational settings to address questions of *how, why,* and *where* Care Transitions interventions succeed or fail to achieve intended outcomes and whether its components can be replicated and scaled to other settings. Investigators can apply the CF-CT to a whole intervention with various distinct parts or to one or more those parts. The primary users of this framework are investigators and practitioners who wish to design a study or evaluation project.

A key focus of current health care policy is interventions for transitions from the acute hospital to the ambulatory setting, which can involve predischarge interventions in the hospital setting, such as patient/caregiver education; postdischarge interventions, such as outreach to patients; and bridging interventions, which include both types of elements. The taxonomy used in several previous systematic literature reviews on Care Transitions[26] categorizes different types of transitional care interventions and includes key activities (or components) from the perspective of the hospital. Importantly, because this taxonomy (and most current research) is from the hospital perspective, and therefore does not address community-based interventions comprehensively, we have not included the development of relationships with common postdischarge followup sources or outpatient-based care management or primary care interventions.

We used feedback obtained from a literature scan, experts familiar with the CFIR, and a multidisciplinary Technical Expert Panel (TEP) that examined the framework objectively during a series of calls. The team critically assessed each component of the CFIR and its adaptation to PCMH to produce a tailored contextual framework incorporating this feedback.

This remainder of this chapter is organized into four sections. Adaptation Methods describes how we adapted and refined the CF-PR and CF-PCMH to Care Transitions interventions to develop the CF-CT. The Organization of the CF-CT section describes briefly the domains of the CF-CT, and orients users to the graphic representation. The How to Use the CF-CT section gives users a roadmap for approaching the multiple, complex dimensions of the CF-CT. Tables 17 through 23 describe the domains, constructs, and subconstructs of the CF-CT. This chapter concludes with a case study of a Care Transitions intervention implementation that illustrates application of the CF-CT. See the Glossary of important terms.

Organization of the CF-CT

The CF-CT is a comprehensive menu of implementation research factors, organized into six domains, derived from the original CFIR, and subdivided into more specific categories of constructs and subconstructs. The domains differ from the CFIR and CF-PR and CF-PCMH in several ways. Since Care Transition interventions often cover multiple settings, the Outer Setting is redefined here as the External Context, and since the intervention can involve more than just settings (e.g., community-based organizations), the Inner Setting is redefined as Organizational Characteristics. Outcomes are also included, which were added for the CF-PCMH. The domains are defined as follows:

- **Care Transitions Intervention Characteristics:** The characteristics of the intervention being implemented in a particular organization, including core activities or components (the essential and indispensable elements of the intervention itself) and an adaptable periphery (adaptable elements, structures, and systems related to the intervention and organization into which it is being implemented).
- **External context:** Includes the economic, political, and social context within which an organization(s) resides and that may affect the implementation process.
- **Organizational Characteristics:** Redefined from the CFIR "Inner Setting" domain. Tangible and intangible manifestation of characteristics of the organizations involved in the intervention, including structural characteristics, networks and communications, culture, climate, and readiness that all interrelate and influence implementation. The construct includes both hospital and ambulatory organizations involved in the Care Transitions intervention, as well as other organizations that are core to the intervention (e.g., community-based organizations). Can include the transferring and receiving organizations.
- **Characteristics and Roles of Providers**: Attributes of the individuals (as carriers of cultural, organizational, professional, and individual mindsets, norms, interests, and affiliations) who are engaged in the provision of care or treatment. They may or may not be directly involved in the intervention and/or implementation process.
- **Characteristics and Roles of Patients and Caregivers:** Attributes (individual mindsets, norms, interests, and affiliations) of the individuals and caregivers who are the recipients of care or treatment in the given intervention setting.
- **Process of Implementation**: Processes (including planning, engaging, and reflecting) to achieve individual- and organizational-level use of the intervention as designed.
- **Measures of Implementation**: Qualities of the implementation and descriptions of how the intervention components are actually implemented, within and between organizations, and changes over time. Measurement should involve not just the number and type of interactions with patients and caregivers or between providers, but the content and quality of those interactions. These elements refer to the Proctor et al.[6] "implementation outcomes"; they are intermediate outcomes.
- **Care Transition Outcomes**: The results of the implementation, defined as implementation dimensions, and the targets of the intervention overall.

Researchers could use this framework to define and review the range of potentially relevant concepts and outcomes as they prepare an implementation study. Additionally, they could conduct initial investigations with hospital and ambulatory care providers, administrators, and implementers to determine which constructs are likely to be most useful in the evaluation.

During their research, they may refine their selection of constructs and their specifications of them in response to data that emerge from the field or in response to changes in the intervention process and context that take place during the life course of the intervention. They may also find it useful to refine the subconstructs even further for specific research purposes.

Modifications in the CF-CT

The original intent of the CF-CT was to focus on hospital to ambulatory care settings; however, the TEP recommended including community-based service organizations because these entities play central roles in the successful transition to the home. Ultimately we chose to broaden the focus and emphasize interactions between organizations, reframing constructs to include different organizations within an intervention, increasing emphasis on patients and engagement, and adding and separating out caregiver issues. Below, we provide a brief discussion of domains and constructs that were developed or modified substantially for the CF-CT. For definitions of these constructs, see the CF-CT tables, which begin with Table 17.

- Intervention Characteristics: The construct *adaptability* was also adapted to reflect the frequent need to choose different components into a "bundled" intervention in Care Transitions interventions. Organizations using a named intervention such as STAAR have frequently customized it. Rather than using labels, it is better for the researcher to precisely describe what is being done.
- External Context: This domain was renamed from *outer setting*, as these interventions will often include different settings. Care Transitions rely heavily on *community resources* and so this construct was added.
- Organizational Characteristics: The TEP agreed that the framework should be broader than practice or integrated health care settings (where patients receive care and treatment) and include community-based organizations, such as community coalitions, agencies, and collaboratives. Thus, this domain was renamed from *inner setting*, as these interventions can include different settings as well as other organizations, such as community-based organizations or collaboratives. We also had numerous modifications and additions to this domain.
    - *Accountability* was modified to reflect the shared accountability across and within organizations that are part of the intervention for implementation and success. Within an organization, certain disciplines or units may be more involved than others, and some may not be involved (e.g., nursing leadership, hospitalists, emergency department). External organizations and networks maybe be categorized as belonging to the outer setting, but nonetheless involve accountability in order for the intervention to succeed.
    - *Measurement capability and data availability.* Lack of data or of quality data often leads to failure of the project. Common issues go beyond information technology-related barriers and include measurement differences between organizations; lack of availability or sharing; accountability for collection, documentation, and analysis; and timeliness.
    - *Continuity* was added to emphasize the importance of exchange of information and relationships, between organizations and with patients/caregivers.
- Characteristics and Roles of Individual Providers: Roles was added to this domain to emphasize the importance of provider roles in Care Transition interventions. This domain shares most of the same constructs as those for patients and caregivers; for *parsimony*

they are combined in the table but remain separate in the graphic to emphasize their unique contributions.

- Characteristics and Roles of Patients and Caregivers: TEP members agreed patients should be emphasized in the framework; moreover, caregivers have roles and needs unique from those of patients. We created two new constructs, *patient needs and resources* and *caregiver needs and resources,* to emphasize this distinction.
- Process of Implementation: This domain had a number of notable construct modifications and additions.
    - *Physical space* was adapted to also include *presence of organizations*, as the physical presence of providers/facilitators from other organizations may be key to building and sustaining collaborations.
    - *Engaging relationships between organizations, external context* was added to highlight the significance of the external context in Care Transitions.
    - *Practice roles* was renamed *transition roles* to enhance its resonance to Care Transitions researchers and evaluators.
    - *Integrators* was added as a subconstruct under *transition roles.* Integrators are responsible for building relationships/collaborations between organizations; their role is central to many sponsored Care Transitions programs, such as BOOST.
- Measures of Implementation: The construct of *evolvability* was added to reflect description of adaptations made to the intervention components and how these were implemented. The construct *reach* was further broken down into reach within population and reach within the organization, as the intervention may aim to do one but not the other, or both.
- Care Transition Outcomes: There was no consensus on what patient-centered outcomes should be included, and whether adverse drug outcomes should be considered patient-centered or clinical. We chose to maintain the outcomes developed for the CF-PCMH as they aligned well to the outcomes for Care Transitions. The only change was to redefine *patient-centered outcomes* to include caregivers, and to emphasize achievement of goals and care consistent with preferences.

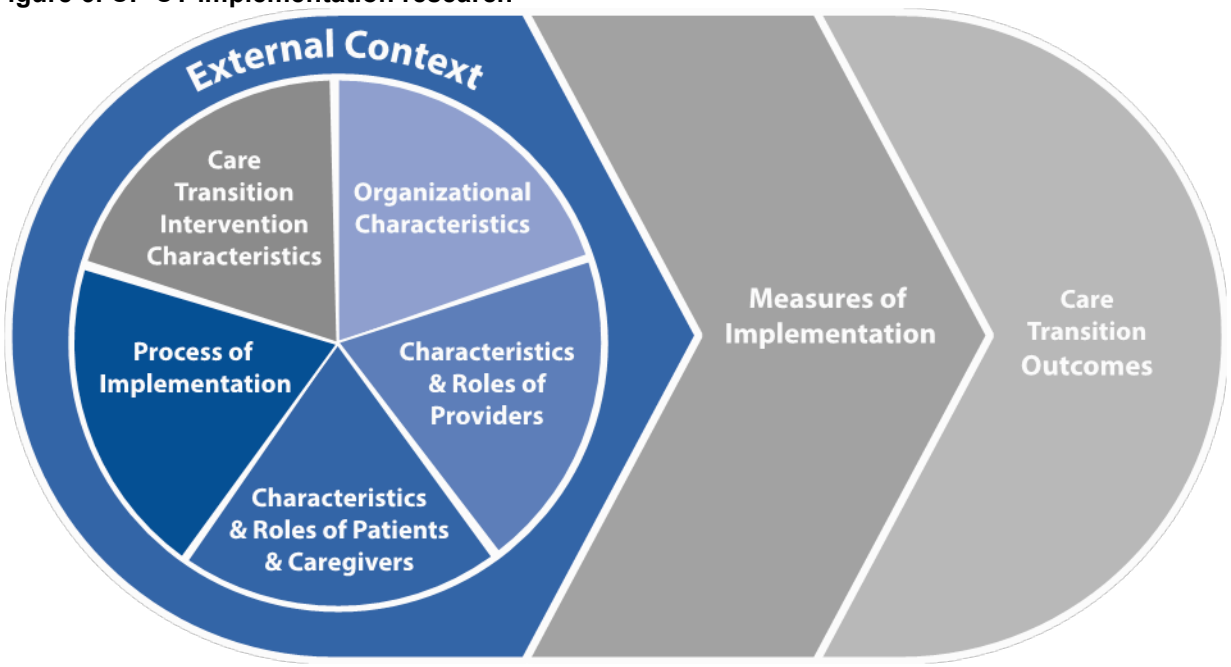
Graphic Representation of the CF-CT

Figure 6 is a graphic representation of the Contextual Framework for Care Transition Interventions (CF-CT). Although all TEP members agreed that patient-centeredness is the ideal, they had different perspectives on whether the graphic should have patients and caregivers at the center. Some argued that intervention design is usually centered around organizations, based on issues such as policies, payment, speed, funding and research opportunities, and are the leaders of this work; institutional outcomes such as readmissions and cost, rather than patient-centered outcomes such as quality of life, are usually the primary goal. For others, the primary reason for the intervention is the patient, and if the intervention cannot be personalized to heterogeneous patient and caregiver needs, it will not be effective. We addressed these comments by creating to distinct areas within the graphic for providers and patients.

On the left side of the figure, the five domains of Care Transition interventions are shown in a circle that includes the attributes of the intervention itself, and the individuals and organizations or systems carrying out the intervention or the target of the intervention. These domains include: Care Transition Intervention Characteristics, Organizational Characteristics, Characteristics and Roles of Providers, Characteristics and Roles of Patients and Caregivers, and

Process of Implementation. The outer ring of the circle represents the External Context, outside the domains of intervention, organizations, and individuals. An arrow to the right of the circle points to the Measures of Implementation, which influence Care Transition Outcomes.

Figure 6. CF-CT implementation research



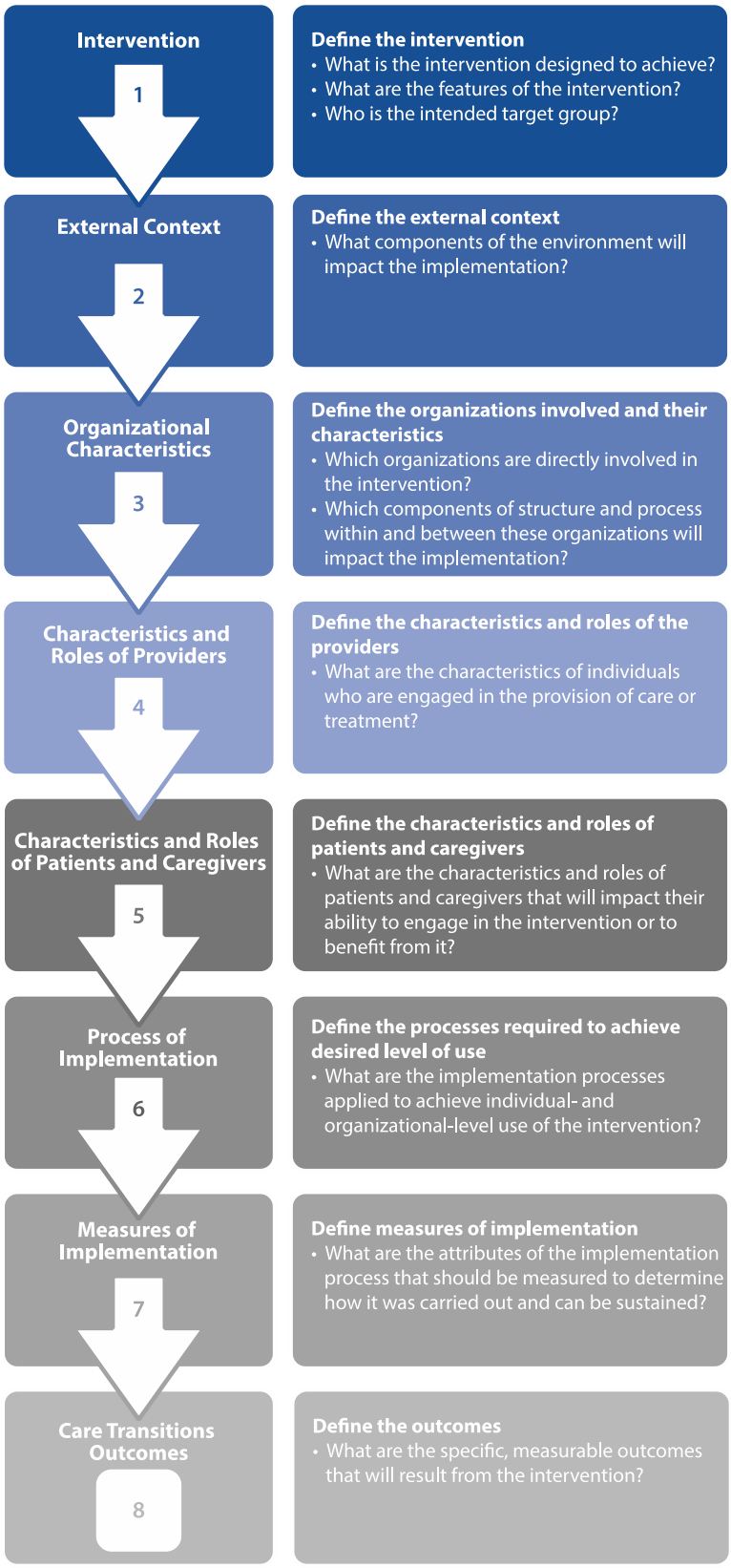
How to Use the CF-CT

The nature of Care Transitions interventions is such that details of development and implementation vary from one context to another, depending on a variety of issues. Therefore, the framework does not prescribe a set of domains or constructs that must be considered during evaluation; rather it provides a comprehensive set of potential items that teams working on Care Transitions interventions research can choose depending on the nature of the research goals and questions.

The following flowchart (Figure 7) presents step-by-step guidance on how this framework can be used. The flowchart presents a series of questions, and each series is tied to a particular domain in the framework (Tables 17 through 23). As these questions are considered, the user should refer to the appropriate domain in the framework table to see which constructs are relevant. For example, Step 1 corresponds to the intervention domain, and as the team considers the various issues related to this domain, they should refer to the framework to choose those constructs relevant to them. As mentioned previously, we do not prescribe which constructs must be selected as a result of the variations between different Care Transitions interventions, given the heterogeneity of settings and clinical conditions encountered in these programs. In particular, in many interventions, the discharging or receiving setting will have little control or relationship with the other setting, as well as little control over the external context. Ideally, interventions would try to create these relationships or links between settings, but this is often not possible. While following this step-by-step process of using the framework, we recommend that users of the framework select qualities, features, or characteristics that are closely tied to intervention

outcomes such as utilization (e.g., readmissions, completion of followup tests) and patient satisfaction with the discharge process (see Outcomes domain in Table 23).

Figure 7. How to use the CF-CT



Abbreviations: CF-CT = Contextual Framework for Care Transitions.

The CF-CT

In Tables 17 through 23**,** we present the CF-CT with brief definitions of the constructs, subconstructs, and examples. Constructs added to the CFIR are labeled as "New" and many other constructs are adapted to better fit with Care Transitions; a few are named differently or included or excluded here based on differences with CF-PCMH and CF-PR, but most are similar. We added clarifying examples for those constructs and subconstructs that were unclear or complex. Each construct or subconstruct is independent and should be applied as appropriate to the research questions and objectives.

Table 17. CF-CT—I. Care Transitions Intervention Characteristics

Construct	Description	Examples
A. Vision and change strategy (NEW)	Proposed changes envisioned by the intervention and the theory of change: how the intervention is supposed to work, what it is meant to achieve/do, and how it is to be executed and articulated through logic models, stated goals, objectives performance measures.	—
B. Targeted groups	Staff and others (vendors, patients) who will be impacted by the intervention.	—
C. Intervention source	Identifying who (which individuals or groups) originated the initiative, and/or from which source the components of the initiative were derived.	—
D. Evidence strength and quality	Target group and other stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have the desired outcomes.	Peer-reviewed, published literature. Guidelines and standards from the National Quality Forum.
E. Relative advantage	Target group and other stakeholders' perceptions of the advantage of implementing the selected intervention instead of other possible interventions.	—
F. Feasibility (NEW)	Target group and other stakeholders' perceptions of the extent to which the intervention components can be successfully used or implemented within the given organization(s).	—
G. Adaptability	Target group and other stakeholders' perceptions of the degree to which the intervention can be adapted, tailored, refined, or reinvented to meet local needs. Capacity to change course (undo or change implementation) if warranted.	—
H. Trialability	Target group and other stakeholders' perceptions of the ability to test components of the intervention on a small scale in the organization(s).	—
I. Complexity	Target group and other stakeholders' perceptions of the perceived difficulty of implementation, reflected by duration, scope, centrality, and intricacy and number of steps required to implement, as well as number of organizations involved and relationships between them.	Bundle of complementary activities (complex intervention) compared with specific activities (e.g., discharge planning); or single-setting vs. bridging or multiorganizational interventions.

(continued)

Table 17. CF-CT—I. Care Transitions Intervention Characteristics (continued)

Construct	Description	Examples
J. Compatibility (NEW)	Target group and stakeholder perception of the alignment of the meaning, values, and norms attached to Care Transitions with those held by members of the organization(s)[17]	—
K. Radicalness (NEW)	Target group and other stakeholder perceptions of the degree of difference between the envisioned change in the processes of Care Transitions and the current state. The degree of disruption to the current state required.[7]	—
L. User control (NEW)	End users' authority/skill to fix a problem on their own.	—
M Location of intervention activity (NEW)	External services, supplemental providers, or new provider roles used to carry out the Care Transitions intervention.	Case management, phone calls, home visits.
N. Design quality and packaging	Degree to which interventions within a bundle or program are well specified and well aligned with one another	A standardized intervention such as Project RED (Re-Engineered Discharge).
O. Workflows (NEW)	Tasks and workflows, including interdependencies between them that are the focus of the intervention or will be affected by it.	Medication reconciliation, outreach to patients.
P. Task/process standardization (NEW)	Degree to which the intervention seeks to standardize tasks and processes that require iterative consultation.	—
Q. History (NEW)	Experiences with similar interventions within the organizations or within the target groups.	The maturity, breadth, and depth of QI activities within the unit/organization(s).[8,9]

Abbreviations: CF-CT = Contextual Framework for Care Transitions.

Table 18. CF-CT—II. External Context

Construct	Description	Examples
A. External networks, partnerships, and systems	Affiliation of the organization(s) with a health care system, network, or other entity (such as a collaborative) that can support the intervention or has existing networks and partnerships that can support the intervention.	Improvement collaborative.
B. External pressure	Pressure emanating from outside the organization to implement the intervention.	Key peer or competing organizations have implemented care transitions.
C. External policy incentives and disincentives	External (State and Federal) policies, laws, regulations, and guidelines that promote or undermine the intervention.	Affordable Care Act, nonpayment for readmissions.
D. Technological environment (NEW)	The technological trends and movements and the availability of technological innovations that may affect the intervention and its context.	Electronic medical record compatibility, health information exchange, social media.
E. Population needs and resources (NEW)	The prevalence of conditions and disease in the population served and the characteristics of the community that are determinants of health status. Also includes other types of transitions and organizations not involved as key components of the intervention (e.g., transfers to subacute rehabilitation).	Health determinants can influence tension for change (e.g., interventions may be more critical in populations with high rates of chronic disease or multiple chronic diseases).
F. Community resources—(NEW)	Availability and access of service providers, aging resources, and multiple levels of community services and supports not directly involved in the intervention.	—

Abbreviations: CF-CT = Contextual Framework for Care Transitions.

Table 19. CF-CT—III. Organizational Characteristics

Construct	Description	Examples
A. Structural characteristics	Social architecture, age, maturity, size, and composition of the organization(s).	—
B. Networks and communications	Nature and quality of networks and formal and informal communication and information exchange within the organization(s), among the involved organizations, and with patients and caregivers.	Linkages between providers, units, the hospital and ambulatory setting, and other involved organizations, and ability to navigate among them.
C. Culture	Norms, values, and basic assumptions of given unit(s) or organization(s) that affect views of the intervention and its implementation.	—
D. Implementation climate	Capacity or reserve [10] for change and the shared receptivity of involved individuals to the intervention..	—
D1. Tension for change	Degree to which stakeholders perceive the current situation as intolerable or needing change.	—
D2. Mandate	Whether compliance with the intervention is expected within the organization.	—
D3. Accountability	Whether entities are subject to tangible consequences for noncompliance.	—
D4. Relative priority	Individuals' shared perception of the importance of the intervention and its components within the organization(s).	—
D5. Organizational incentives	Extrinsic incentives and rewards offered to implement the intervention.	—
D6. Learning climate (NEW)	Organization's willingness to promote trial and error, test new methods, and innovate.	
E. Readiness for implementation	Tangible and immediate indicators of organizational commitment to its decision to implement Care Transitions.	—
E1. Leadership engagement	Degree of commitment, involvement, and accountability of leaders and managers from various disciplines and units to quality and safety improvement, in general, and to the intervention components, specifically.	—
E2. Staff commitment (NEW)	Degree of commitment, involvement, and accountability of physicians, nurses, and other staff to quality and safety improvement, in general, and to the intervention components, specifically.	The degree of clinician, staff, and patient involvement in transition planning.
F. Information access	Ease of access to digestible, applicable information and knowledge about the intervention and its implementation elsewhere and its transmission through training and education.	—
G. IT and HIT resources (NEW)	Technological infrastructure in place to support electronic information management, including IT that crosses organizations.	—
G1. Health IT (HIT) systems	Electronic information management infrastructure and technologies available to clinicians to manage patient care, data, and communications.	Decision support tools, e-prescribing, electronic health records.
G2. IT systems	Technological systems and capabilities to support care transitions.	Interoperability, health information exchange.

(continued)

Table 19. CF-CT—III. Organizational Characteristics (continued)

Construct	Description	Examples
G3. HIT/IT accessibility (NEW)	Includes features of the physical, technical, and social environment in the organization that determine the use, accessibility, and acceptability of technology in patient care.[11]	
H. Measurement capability and data availability (NEW)	Availability or ability to obtain or calculate necessary data across organizations. Issues include measurement differences between organizations; sharing; accountability for collection, documentation, and analysis; and timeliness. Using standard measures can help.	Standard interventions such as BOOST often include easy-to-aggregate measures or tools to capture the elements of the intervention.
I. Training and education (NEW)	General level of resources dedicated to training and education available within the organization(s).	—
J. Other resources (NEW)	Resources for implementation and ongoing operations to support change and innovation, including grant or other Care Transitions-specific funding.	Money, physical space, equipment, staff time.
K. Patient self-management infrastructure (NEW)	Training, counseling, and education available to patients to manage their condition in both hospital and ambulatory settings and through other organizations post-discharge, or resources that cross organizations.	—
L. Continuity (NEW)	Includes information continuity (exchange of information) and relationship continuity, both with provider and patients/caregivers and across organizations.	—
M. Patient/Caregiver centeredness (NEW)	Extent to which patient and caregiver needs are known and prioritized by the organization(s). The resources and services in place to meet those patient needs.	—

Abbreviations: CF-CT = Contextual Framework for Care Transitions; HIT = health information technology; IT = information technology; QI = quality improvement.

Table 20. CF-CT—IV. Characteristics and Roles of Providers, Patients and Caregivers

Construct	Description	Examples
A. Knowledge and beliefs	Individual attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.	—
B. Skills and competencies (NEW)	Degree of relevant expertise, skills, and competencies within the implementing team, unit, and organization. The gap between the current state and the skills and competencies needed to implement the intervention successfully.	—
C. Role (NEW)	Individual's role and responsibility for the intervention. The degree of multiple or shared roles.	Patient is expected to meet with a patient navigator monthly and can make appointments.
D. Authority (NEW)	Individual provider's perceived and actual degree of authority to make decisions and act autonomously.[12]	—
E. Self-efficacy	Individual provider's belief and confidence in his/her capacity to execute the courses of action necessary to achieve intervention goals.	—
F. Collective efficacy (NEW)	Collective belief and conviction of individuals involved that the intervention can be carried out in cooperation with others,[13] including collective efficacy within the care transition team, family, or caregiver support network.	—
G. Stage of change	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained application of the intervention.	—
H. Identification with organization(s)	How individuals perceive the organization(s) and their relationship and degree of commitment with that organization(s),including the broader interorganizational partnerships involved in the intervention.	Patient trust in their usual source of care versus a new case management service
I. Socioeconomic Demographics (NEW)	Characteristics related to the individual's socioeconomic status.	Age, race, gender, occupation, insurance status.
J. Patient needs and resources (NEW)	Patient priorities for health and health care and the social and economic resources to address those priorities.	Need for self-management, need for care coordination.
K. Caregiver needs and resources (NEW)	Caregiver priorities for health and health care and the social and economic resources to address those priorities.	Caregivers support groups.
L. Other personal attributes	Other personal traits not captured elsewehere.	Tolerance of change, social network support, quality of relationship between patient and caregiver.

Abbreviations: CF-CT = Contextual Framework for Care Transitions.

Table 21. CF-CT—V. Process of Implementation

Construct	Description	Examples
A. Planning	Degree to which an implementation scheme for the intervention or methods and specific implementation steps or tasks are developed in advance; the quality of those schemes or methods.	—
A1. Assessing (NEW)	Formal assessment of Care Transitions issues; the needs of the users; barriers to change; the timing of these activities relative to implementation.	—
A2. Goal-setting	Written goals, objectives, benchmarks, and timelines for Care Transitions activities and their feasibility and adequacy.	—
A3. Feedback	Procedures used to provide feedback to stakeholders.	
A4. Contingency planning (NEW)	Plans for adjusting staff schedules and patient loads and increasing the availability of resources to meet the demands of implementation; plans for possible adaptation over time by laying out various scenarios and outcomes.	—
B. Acquiring and allocating resources (NEW)	Resources dedicated to implementing the intervention; the adequacy of those allocations.	—
B1. Training and education	Resources dedicated specifically for training and education to carry out the intervention.	—
B2. Physical space and presence of organizations	Physical space and equipment dedicated to or impacted by the intervention, including.	Designated space to hold cross-organizational care team meetings. Office space for case managers at the hospital.
B3. HIT and IT	Hardware, software, and technology dedicated/upgraded to support the intervention and their adequacy.	—
B4. Staff time	Staff time dedicated to implement the intervention.	Time given to staff to attend trainings and learn transition procedures
C. Process ownership (NEW)	Directionality of leadership (bottom-up or top-down).	—
D. Transition roles (NEW)	Roles of individuals involved in the decision to adopt, execute, and facilitate the intervention.	Case managers, navigators, social service providers.
E. Organizational leaders (NEW)	Individuals who have the role and authority to dedicate resources for the intervention, mandate its implementation, and make decisions to maintain or abandon it.	—
E1. Opinion leaders	Individuals who have influence (positive or negative) on the attitudes and beliefs of their colleagues with respect to implementing interventions.[14,16] Opinion leaders include experts and peers.[15]	—
E2. Formally appointed implementation leaders	Individuals who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, facilitator, or other similar role.	—
E3. Champions	Individuals who dedicate themselves to galvanizing and maintaining support for the intervention and overcoming indifference or resistance that the intervention may provoke.	—

(continued)

Table 21. CF-CT—V. Process of Implementation (continued)

Construct	Description	Examples
E4. External change agents	Individuals outside the organization who can facilitate or undermine decisions about adoption and implementation.	Health plans, other health care systems, collaboratives, policymakers.
E5. Frontline staff (NEW)	Administrative staff, providers (within and outside the organization) who will carry out the intervention or be affected by it.	—
E6. Integrators (NEW)	Individuals in the involved organization(s) with the role of building relationships between the organizations and facilitating bridging needs of the intervention.	—
E7. Patients, caregivers and other stakeholders (NEW)	Patient and his/her family members, and members of the family's support network.	—
F. Engaging	Processes involved in attracting and involving appropriate individuals in the implementation and use of the intervention.	Patient facilitation, navigation, outreach, and followup across organizations.
F1. Engaging/relationships between organizations, external context (NEW)	Engaging, coordinating, crossing boundaries, and developing or capitalizing on relationships to providers, leaders, and frontline staff in organizations involved in the intervention, as well as the external context (other providers, resources, funders).	—
G. Executing	Extent to which those involved carry out and accomplish the implementation according to plan.	—
G1. Decisionmaking (NEW)	Manner in which decisions are deliberated upon within the unit or organization and the diversity of roles involved in the decisionmaking.[9]	—
G2. Staging and iteration (NEW)	Degree to which the Care Transition is carried out in iterative, incremental steps or implemented in its entirety within a specified period.	—
H. Reflecting and evaluating	Quantitative and qualitative feedback about the progress and quality of the process of achieving shared understanding and participation[17]—"reflexive monitoring" and the degree to which it is attained.	Project monitoring, systematic feedback processes.

Abbreviations: CF-CT = Contextual Framework for Care Transitions; HIT = health information technology; IT = information technology.

Table 22. CF-CT—VI. Measures of Implementation (New Domain)

Construct	Description	Examples
A. Acceptability (NEW)	Degree to which intervention goals, strategies, tactics, and specific activities are agreeable, palatable, or satisfactory.	—
B. Adoption/abandonment (NEW)	Intention, initial decision, or action to employ or cease the intervention.	—
C. Appropriateness (NEW)	Degree of fit of the intervention for the given organization(s), discipline, provider, or consumer and/or the relevance of the intervention for addressing specific issues or problems.	—
D. Intervention cost	Costs of the intervention and costs associated with implementing that intervention, including investment, supply, and opportunity costs.	—
E. Fidelity (NEW)	Degree to which the intervention was implemented as originally designed by those who developed and/or introduced it to the organization.	—
F. Reach (NEW)	Absolute number, proportion, and representativeness of individuals who are willing to participate in a given Care Transition initiative, intervention, or program.[18]	Percentage units within a hospital that use discharge planning.
F1. Reach within the population (NEW)	Number of people reached, the improvement for those people reached, and the impact on the population overall.	—
F2. Reach within the organization (NEW)	Absolute number, proportion, and representativeness of individuals who are willing to participate in the intervention, including different disciplines, units, and organizations.[18]	—
G. Penetration (NEW)	Depth of integration of the intervention within an organization involved in the intervention and its subsystems.	Percentage of time a discharge document is transmitted to the accepting provider.
H. Replicability(NEW)	Plans, timing, and/or method of spread (how the intervention is spread within and beyond the involved organizations).	—
I. Sustainability (NEW)	Extent to which changes resulting from the intervention are maintained or institutionalized within the organization(s)' ongoing, stable operations.	—
J. Evolvability (NEW)	Extent to which the change is capable of being sustained through adaptation and refinement.	—

Abbreviations: CF-CT = Contextual Framework for Care Transitions.

Table 23. CF-CT—VII. Care Transitions Outcomes (New Domain)

Construct	Description	Examples
A. Patient and caregiver-centered outcomes (NEW)	Patient and caregiver defined goals and care consistent with patient and caregiver preferences	Patient and caregiver would rather be catherized in the hospital than at home or be seen by a physician rather than a nurse practitioner.
B. Patient/caregiver experience (NEW)	Impact of the intervention on patient/caregiver experiences with care, including satisfaction with care and patient/caregiver-provider interactions.[17]	—
C. Provider experience (NEW)	Effect(s) of the intervention on a provider's burden of effort and quality of work life, including provider communication/collaboration.[17]	—
D. Processes of care (NEW)	Key measurable processes of Care Transitions interventions.	—
D1. Patient-centered (NEW)	Extent to which the intervention provides enhanced access to and continuity of care, collaborates with patients and family to develop and manage care plans, provides resources to support self-care, and is engaged in performance improvement.[19]	—
D2. Coordinated (NEW)	Extent to which the intervention tracks; follows-up on; and coordinates tests, referrals, and care at other facilities; the extent to which the practice follows up with discharged patients.[19]	—
D3. Comprehensive (NEW)	Extent to which the intervention is responsible for satisfying all the medical needs of a patient, including prevention and specialty care.[20]	—
D4. Accessible (NEW)	Extent to which the intervention delivers routine/urgent care and clinical advice during and after business hours; provides electronic access; allows patients to select a clinician; and is focused on team-based care with trained staff.[19]	—
D5. Quality (NEW)	Extent to which the intervention shows an on-going commitment to high quality through the use of performance measurement, evidence-based strategies, etc.[20]	—
D6. Safety (NEW)	Extent to which the intervention collects and uses safety data, and shares such data publicly as a marker of ongoing commitment to safety and quality.[20]	—
E. Effectiveness (NEW)	Extent to which the intervention contributes to providing services to all who could benefit, without providing services to those who would not.	—
F. Timeliness (NEW)	Extent to which the intervention contributes to reducing wait times and delays, both for those who provide care and those who receive it.	—
G. Clinical outcomes (NEW)	Result of a medical intervention as captured by changes in health status.	—
H. Health care utilization (NEW)	Utilization related to Care Transitions, such as readmissions, redundant tests/procedures, and post discharge provider visits.	—
I. Cost effects/impact (NEW)	Cost impact of the intervention (summative or incremental) resulting from changes in health care utilization and efficiency. Includes fixed and variable costs.	—

(continued)

Table 23. CF-CT—VII. Care Transitions Outcomes (New Domain) (continued)

Construct	Description	Examples
J. Perceived value (NEW)	The expected and experienced improvements in better health care, improved quality of life, and improved professional collaboration.	—
K. Unintended consequences (NEW)	Emergent, interim, or longer-term outcomes that were unanticipated and usually not desired.	—

Abbreviations: CF-CT = Contextual Framework for Care Transitions.

Applying the CF-CT: A Case Study

Below is an adapted version of a case study from the Robert Wood Johnson Foundation's Aligning Forces for Quality program.[27] The RTI-UNC EPC is not the author of this case study and does not possess any copyright to this work. We use this modified example below to illustrate how the CF-CT may be used.

Reducing Readmissions and Integrating Care in Cincinnati

Cincinnati is home to several hospitals and physician groups that eagerly compete with each other for market share. The Health Improvement Collaborative of Greater Cincinnati Alliance, sponsored by the Robert Wood Johnson Foundation Aligning Forces for Care Quality (AF4Q), has found that its clinicians need to work together to coordinate care. This effort (henceforth referred to as the Collaborative) partnered with the local hospital association and the Greater Cincinnati Health Council to reduce heart failure readmissions under a program called Accountable Care Transformation, or ACT.

ACT consists of 19 hospitals and health systems, which formed a collaborative to reduce readmissions by 10 percent by adopting five best practices:

1. Upon admission, implement a risk assessment tool with a focus on heart failure to identify patients who are at high risk of readmission from social factors.
2. Use the teach-back method during the hospital stay from admission to discharge during key clinical interventions.
3. Provide real-time handover communications.
4. Address timely physician followup (appointment to occur within 5 to 7 days of discharge).
5. Follow up with the patient or primary care giver (or emergency contact) within 48 to 72 hours of discharge via telephone or home visit.

The five practices draw from a variety of sources including Project BOOST, the STAAR Initiative, and the Institute for Healthcare Improvement. The ACT rests on two core principles: collaboration and transparency. The Collaborative is regional because patients cross routinely from one community within the Cincinnati region to another. Nor is the Collaborative bound by hospital structures; even within a competitive environment, hospitals have to share data and communicate with one another in order to adhere to the five practices.

According to the medical director of the Collaborative, implementation and evaluation have been challenging. The Collaborative is not receiving data in real time, which creates delays in the implementation timeline. This lag in data submission also has hampered the Collaborative's ability to track dollars saved and number of readmissions reduced; however, self-reported data from hospitals participating in the ACT indicate a downward trend in readmissions. The medical director added, "But regardless of whether we meet our goal, the journey and the process has been so helpful and has improved care for patients in our communities."

Applying the CF-CT

Below, we apply the flowchart to the case study, selecting a few constructs as examples for each step.

Step 1—Define the intervention.

- What is the intervention designed to achieve?
  The goal of this intervention is to reduce heart failure readmissions. In a broader sense, the intervention is building a collaborative and working to coordinate care across disparate organizations.
- What are the features of the intervention?
  The intervention for this case has five key elements, all adapted from established Care Transitions programs but rebundled for this collaborative:
  1. Implement a heart failure readmission risk assessment tool.
  2. Use the teach-back method during key clinical interventions.
  3. Provide real-time handover communications.
  4. Address timely physician followup.
  5. Follow up with the patient or primary caregiver after discharge.
- Who is the intended target group?
  Relevant constructs may include *feasibility* (e.g., can all these elements realistically be carried out at all hospitals, including issues of cost-effectiveness), *complexity* (e.g., difficulty of implementing five disparate elements of the intervention which will require involvement of a number of providers, including training), and the *workflows and task/process standardization* that will be needed to incorporate tasks such as teach-back into daily care.

Step 2—Define the external context

- What components of the environment will impact the implementation?
  Key constructs for external context may include *external networks*, or existing relationships with outpatient providers who will need to see the patient in a timely way to achieve timely physician followup (element #4), and the *external pressures* and policy incentives to reduce heart failure readmissions.

Step 3—Define the organizations involved and their characteristics

- Which organizations are directly involved in the intervention?
  For this case, this includes the 19 hospitals and health systems, as well as the community and national organizations: the Health Improvement Collaborative of Greater Cincinnati, Greater Cincinnati Health Council (hospital organization), and the Robert Wood Johnson Foundation.
- Which components of structure and process within and between these organizations will impact the implementation?
  Key structural characteristics may include the size and organizational resources of the various 19 hospitals, which could influence their capacity, internal support, and ability to be flexible enough to make the multiple changes needed. The *implementation climate* could affect how willing the individual organizations are to change care processes to improve Care Transitions. Other important constructs include individual organizational *accountability* for reducing heart failure readmissions in the larger collaborative, relative priority within the organizations to dedicate to the elements of the intervention as compared *to relative priorities,* and *leadership engagement* to support the organizations and staff in implementing the intervention. *Measurement capability and data availability* are particularly important for Care Transitions interventions; in this case, outcomes could

not be evaluated due to issues with accessing data from the various organizations involved.

Step 4—Define the characteristics and roles of the providers

- What are the characteristics of individuals who are engaged in the provision of care or treatment?
  For this intervention, *provider roles* may be particularly important, as new roles (especially discharge followup) need to be developed within each organization. *Collective efficacy* that the intervention can be achieved is needed at the individual and organizational as well as the collaborative level.

Step 5—Define the characteristics and roles of patients and caregivers

- What are the characteristics and roles of patients and caregivers that will impact their ability to engage in the intervention or to benefit from it?
  The importance of *patient needs and resources* are reflected in the first element of the intervention – risk assessment for readmission, including social factors – and these factors may affect the implementation of the intervention and readmission outcomes. *Knowledge* and *skills and competencies* are important for the effectiveness of the teach-back method and phone followup, and social factors such as access to transportation and a telephone could affect physician followup.

Step 6—Define the processes required to achieve desired level of use

- What are the implementation processes applied to achieve individual- and organizational-level use of the intervention?
  For this case, *planning* is important, with the elements of the intervention chosen from existing programs and rebundled for this collaborative. *Engaging* patients and caregivers and providers is also critical, with important information exchange in teach-back and postdischarge phone calls for patients/caregivers, and effective handoff communication with providers.

Step 7—Define measures of implementation

- What are the attributes of the implementation process that should be measured to determine how it was carried out and can be sustained?
  In Care Transitions interventions, specific elements may not be implemented as planned, or may require adjustment during implementation or after initial evaluation. Evaluating what was actually implemented and the measures of implementation are critical to understanding the intervention and outcomes. Potentially useful aspects to be measured reflect many of the constructs described above, including *acceptability* of the intervention among stakeholders and the *fidelity* of how each element was implemented in each organization and across organizations; *reach within the organization* would examine the providers involved in care of the patients, while *reach within the population* would examine patients and caregivers. Better measurement of the implementation process might help to identify barriers as well as solutions effective in some organizations that could be helpful to others.

Step 8—Define the outcomes

- What are the specific, measurable outcomes that will result from the intervention?
  In this case, the focus was on readmissions as an outcome of *health care utilization*, but many other possible outcomes could have been relevant, including patient and caregiver-centered outcomes such as achieving *patient and caregiver-centered outcomes*; the *patient/caregiver experience of care; cost effects;* and *unintended consequences*, such as the burden of the substantial investment required for followup postdischarge.

Discussion

In this chapter, we reflect on the experience of adapting the Consolidated Framework for Implementation Research (CFIR) to three different types of complex system interventions, highlighting the similarities we uncovered in the needs, issues, and concerns voiced by the Technical Expert Panels (TEPs) and guidance we can offer to researchers wishing to adapt the CFIR to other forms of complex system interventions.

The systems in which process redesign for efficiency and cost reduction, Patient-Centered Medical Homes (PCMH), and Care Transition interventions might be applied can aptly be described as nonlinear, dynamic, and composed of a multitude of "massively entangled" entities.[28] Most researchers of these interventions (our TEP members among them) would agree that these interventions are "complex." Yet we lack a common vocabulary for capturing this complexity. To understand the interplay of people, settings, technology, and policy to effect some desired outcome or impact, researchers require a common taxonomy.

We identified the CFIR, adapted to the requirements of each intervention, as a potential solution to this dilemma. The CFIR draws from a wide range of disciplines and is theoretically agnostic. This feature of the CFIR makes it suitable for the study of complex system interventions, which inherently benefit from a multidisciplinary approach. The CFIR's broad range of constructs encompass most of the contextual dimensions of the three interventions we adapted. The TEPs found the original constructs in the CFIR to be relevant across the three adaptations. However, the literature scan and the TEP input resulted in adding several dozen new constructs to the Contextual Framework for Process Redesign (CF-PR) and PCMH (CF-PCMH) and two new domains. The Contextual Framework for Care Transitions-(CF-CT) integrated these inputs and added several new constructs of its own. Table 24 presents these new constructs and subconstructs by framework. The original CFIR constructs required mostly modest revisions to the definitions and construct name. The CFIR construct *design quality and packaging* was dropped from the CF-PR and CF-PCMH but retained in the CF-CT; Care Transition interventions have packages (e.g., RED, Project BOOST) with established steps and protocols, whereas this is less the case for process redesign and PCMH.

Table 24. New Framework Constructs

Domain Construct /*Subconstruct*	**CF-PR**	**CF-PCMH**	**CF-CT**
Intervention Characteristics	—	—	—
Vision and change strategy	✓*	✓	✓
Feasibility	✓	✓*	✓
Compatibility	✓*	✓	✓
Radicalness	✓*	✓	✓
User control	✓*	✓	✓
Workflows	✓*	✓	✓
Task/process standardization	✓*	✓	✓
History	✓	✓*	✓
Location of PCMH activity (location of intervention activity in CF-CT)	—	✓*	✓
Outer Setting (External Context in CF-CT)	—	—	—
Technological environment	✓*	✓	✓
Population needs and resources	—	✓*	✓
Community resources	—	✓	✓*

(continued)

Table 24. New framework constructs (continued)

Domain Construct /*Subconstruct*	**CF-PR**	**CF-PCMH**	**CF-CT**
Inner Setting (Organizational Characteristics in CF-CT)	—	—	—
Staff commitment	✓*	✓	✓
IT and HIT resources	✓*	✓	✓
Human factors (*HIT/IT accessibility* in CF-PCMH)	✓*	✓	—
Other resources	✓	✓*	✓
Training and education	✓*	✓	✓
Patient centeredness	—	✓*	✓
Measurement capability and data availability	✓	✓	✓*
Patient self-management infrastructure	—	✓*	✓
Continuity	—	✓	✓*
Characteristics of Individuals and Teams (Characteristics and Roles of Providers and Patients in CF-CT)	—	—	—
Skills and competencies	✓*	✓	✓
Role	✓	✓*	✓
Authority	✓	✓*	✓
Collective efficacy	✓	✓*	✓
Socioeconomic demographics	—	✓	✓
Patient needs and resources	✓	✓	✓*
Caregiver needs and resources	—	✓	✓*
Process of Implementation	—	—	—
Assessing	✓	✓*	✓
Contingency planning	✓	✓*	✓
Acquiring/allocating new resources	✓	✓*	✓
Process ownership	✓	✓	✓
Engaging/relationships between organizations, external context	✓	✓	✓*
Organizational leaders	✓	✓*	✓
Frontline staff	✓	✓*	✓
Facilitator	✓	✓*	✓
Integrators	—	—	✓*
Patients and other stakeholders	✓	✓*	✓
Decision making	✓	✓*	✓
Staging and iteration	✓*	✓	✓
Measures of Implementation	—	—	—
Acceptability	✓	✓	✓
Adoption/abandonment	✓	✓	✓
Appropriateness	✓	✓	✓
Implementation cost	✓	✓	✓
Fidelity	✓	✓	✓
Reach	✓	✓	—
Reach within the population	✓	✓	✓*
Reach within the organization	✓	✓	✓*
Penetration	✓	✓	✓
Replicability	✓	✓	✓
Sustainability	✓	✓	✓
Evolvability	✓	✓	✓*
Outcomes	—	—	—
Cost effects/impact	✓*	✓	✓
Perceived value	✓*	✓	✓
Unintended consequences	✓	✓*	✓
Processes of care	—	✓*	✓
Patient-centered	—	✓*	✓

(continued)

Table 24. New Framework Constructs (continued)

Domain Construct /*Subconstruct*	**CF-PR**	**CF-PCMH**	**CF-CT**
Coordinated	—	✓*	✓
Comprehensive	—	✓*	✓
Accessible	✓	✓*	✓
Quality	✓	✓*	✓
Safety	✓	✓*	✓
Effectiveness	✓	✓	✓
Timeliness	✓	✓	✓
Efficiency	✓	—	—
Patient and caregiver-centered outcomes	—	✓	✓*
Patient/caregiver experience	✓	✓*	✓
Provider experience	✓	✓*	✓
Clinical outcomes	—	✓*	✓
Health care utilization	✓	✓*	✓

*Indicates the original source of the construct or subconstruct.
Abbreviations: CF-CT = Contextual Framework for Care Transitions; CF-PCMH = Contextual Framework for Patient-Centered Medical Homes; CF-PR = Contextual Framework for Process Redesign; HIT = health information technology; IT = information technology; PCMH = Patient-Centered Medical Home.

Using the CFIR to conceptualize the multiple layers and complex interactions and networks that characterize complex system interventions was more difficult. Many of the elements of context can vary by time, location, and organizational unit (e.g., individual, team, practice, organization, system). This limitation of the framework became especially apparent in the Care Transitions area, as these interventions cannot even be defined as having a narrowly defined location or setting. Interventions that are essentially a multiagency collaborative or a community-based entity that provides coordination across multiple providers are not bounded by place or organization. In this case the TEP had difficulty distinguishing the "outer setting" from the "inner setting." Accordingly, we dropped the term "inner setting" altogether from the CF-CT and regrouped its constituent parts into new domains.

In the initial versions of the CF-PR and CF-PCMH, we included samples of constructs in two- and three-dimensional tables to orient the researcher to the multidimensional attributes of constructs and to discourage the tunnel vision that can occur when context is examined from only one perspective. These sample tables failed to resonate with the TEPs, who found them on the whole confusing and unhelpful. The adapted frameworks in their current form, confined to text-based two-dimensional tables, do not lend themselves to the levels of abstraction possible with complex systems. A Web-based tool that allows the user to explore the various hierarchies within a construct and juxtapose them against two or more dimensions (e.g., time by location) may come closer to achieving the original intent of our sample tables.

The adapted frameworks, due to the breadth and relevance of the constructs included, should acquaint the researcher or the implementing organization with the large range of contextual variables that are possible and important to consider in a study or evaluation. The adapted frameworks can be used by investigative teams planning multisite studies or funders supporting a portfolio of grants to deliberate on the core constructs needed for cross-site analysis. However, we recognize that the sheer number of constructs can be overwhelming and at the TEPs' suggestion we added a general roadmap to guide the construct selection process. As every study is unique, there is no simple recipe for construct selection. Much like the interventions, the decision to include or leave out specific constructs is rooted in the context of the study itself.

Cross-Cutting Issues

In the remainder of this chapter, we present a number of the common issues or concerns we encountered in two or more of the adaptations. Some of these we addressed in the frameworks. Others remain unresolved or may have no clear solution, but are nevertheless important to keep in mind. These issues are as follows:

- *Components of the intervention*. Complex system interventions are typically not a single intervention but a collection of interventions, so issues of scope and boundary are critical to address early in study design. Process redesign interventions like Lean and Six Sigma can be especially confounding because they are organization-wide initiatives; researchers must decide whether to apply particular constructs (e.g., complexity and relative advantage of intervention) organization-wide, to specific projects, or to both.
- *Components of the intervention vs. targets of the intervention*. Disentangling the intervention from its context for research purposes can be an onerous task. Elements of the framework that are usually considered the context within which an intervention occurs can also become the targets of an intervention—for example, when process redesign seeks to alter team interactions or change culture and learning climate. Defining exactly what elements constitute the intervention and its objectives would seem a critical first step in using the framework. Unless the intervention specifies a specific causal pathway with well-articulated goals and objectives, the activities or outputs of the intervention could easily be confused with the outcomes. A new "Vision/Change Strategy" construct was added to distinguish the intervention from its context.
- *Bundled nature of many interventions.* The bundling of intervention components drawn from different programs is a key element in these interventions; bundling is important for evaluating which parts of the bundle were implemented and which parts are associated with outcomes, and the relative importance of the components.
- *Intervention timing and research time frame*. Complex system interventions rarely have a defined start and end date. As several TEP members noted, implementation may be more of an iterative process than a linear one that proceeds sequentially through clear stages. The process redesign and PCMH TEPs agreed that the contextual framework should encourage awareness of possible changes in the meaning and relevance of constructs across stages of implementation—even though very little empirical knowledge exists about the long-term implementation of complex interventions. One conceptualization that may be helpful divides the process into three stages: pre-implementation, implementation, and sustainability.[29] Constructs that are relevant to one stage, such as pre-implementation adoption decisions, may be less useful for studying another stage of the same intervention, such as sustainability. Researchers who follow an intervention over time might retain some core constructs across the entire study but select others that apply chiefly to one stage in the life course of the intervention. While considerations of time are relevant to selecting and applying constructs, the TEP noted that it can be difficult to determine when adoption and other stages begin and end.
- *Organizational units and level of analysis*. Complex system interventions may occur in multiple organizational units at the same time. For example, several clinics within the same organization or delivery system may implement similar redesigns aimed at enhancing patient access and throughput. Additionally, redesigns often operate at multiple organizational levels (i.e., levels of analysis). Relevant levels may include individual participants, teams, units, organizations (including autonomous practices), and

delivery systems. The framework may inform research by alerting researchers to the following:

  - The importance of conceptualization and measurement at appropriate levels of analysis and attention to and conceptualization of interactions among actors or units at the same level and across levels. Several TEP members noted that such interactions, along with interactions among multiple aspects of the interventions (and reflected in multiple constructs within the framework), may be as important as the effects of isolated variables.
  - The importance of weighing potential contributions of multilevel analysis against the need to keep the research within manageable proportions.

- *Stakeholder and practice roles*. The CFIR distinguishes among many practice roles, and our discussion with the TEPs led to the addition of yet other roles and to a focus on the diverse internal and external stakeholders involved in and affected by process redesign, PCMH, and Care Transitions. We recognize that constructs may take on different meanings or measured values when applied to different roles or different stakeholders. For example, top management and nurse leaders may assess the value of an intervention of nursing roles very differently. External change agents for an intervention may assess the leadership commitment to the intervention very differently than frontline staff who participate in the initiative.
- *Indicators of implementation success*. Proctor et al.[6] define outcomes for the implementation (e.g., acceptability, adoption, appropriateness, costs, feasibility, preservation, sustainability) as distinct from the outcomes of an intervention. The TEP agreed that specifying these implementation outcomes is a useful addition to the framework. To avoid confusion with clinical outcomes, we opted for the term "indicators of implementation success" to refer to Proctor's implementation "outcomes."
- *Intervention outcomes*. The process redesign and PCMH TEPs recommended adding outcomes to the CFIR, although they did not completely agree on which outcomes to include or what to call them. We added intervention-specific outcomes to each of the three frameworks (several of the outcomes overlap). We kept the outcome constructs general so as to keep the focus of the framework on context and implementation. A large body of literature on many of these outcomes can be used to conceptualize them in more detail.
- *Patient-centered/population health perspectives.* Neither the PCMH nor the Care Transitions TEPs thought the frameworks were sufficiently patient-centered. On the one hand, intervention design is usually centered around organizations, based on issues such as policies, payment, speed, funding, and research opportunities, and organizations are the leaders of this work; institutional outcomes such as readmissions and cost, rather than patient-centered outcomes such as quality of life, are usually the primary goal. On the other hand, the primary reason for a PCMH or Care Transitions intervention is the patient, and if the intervention cannot be personalized to heterogeneous patient and caregiver needs, it will not be effective. The PCMH and Care Transitions TEP members also felt that the framework should emphasize the role of population health. Taking into account these perspectives, we added constructs relevant to patient-, caregiver-, and population-level contexts. We also included patient outcomes.
- *Conceptualizing the framework around settings or organizations.* Complex system interventions are broader than a particular practice or integrated health care setting

(where patients receive care and treatment) and typically can include community-based organizations, such as community coalitions, agencies, and collaboratives. These are often the effector arm and critical to a Care Transitions or PCMH intervention. A key concept to consider is that the intervention is based upon layers of organizations, rather than embedded in a single setting or group of settings.

- *Broader applicability*. Although the primary purpose of the frameworks is to guide research and evaluation, a number of TEP members thought they incorporated issues of concern to implementers and might become a useful tool for practice.

Limitations

The comprehensive series of methods used to develop the CF-PR, CF-PCMH, and CF-CT has a number of strengths, including a set of literature reviews and TEP input sessions. Limitations include the scope of the literature reviews, which could have missed some relevant resources (e.g., by focusing on hospital-ambulatory transitions or searching after 2005 for Care Transition interventions), and limitations on the size of the TEPs to group sizes amenable to discussion, which may have not included some viewpoints. The qualitative, descriptive nature of the input allowed for a rich discussion of the issues, but interpretations of recommendations were made based on discussion; no surveys or other quantitative input was obtained from the TEP. Finally, although we asked the TEPs to consider carefully if and how they would apply the frameworks to their implementation research, real evaluation of these frameworks depends on application in actual practice.

Conclusion

The investigative team took a very open approach to this effort, beginning with a literature scan, discussions with the Agency for Healthcare Research and Quality (AHRQ), and our Technical Expert Panel (TEP). Much of the adaptation protocol was developed during the project and we offer guidance to other researchers wishing to make similar adaptations of the Consolidated Framework for Implementation Research (CFIR).

- **Involve the developers of the framework and those familiar with it.** In our case, we invited one of the lead developers of the CFIR to present the framework to the TEPs. Her participation was especially helpful in orienting the investigative team and the TEPs in the purposes, intent, and application of the framework. We also included TEP members who had used the CFIR, and the team was able to rely on their insights and expertise to address questions or concerns TEP members had about the CFIR.
- **Conduct a literature scan and give it a clear focus**. A full systematic review of the intervention is neither necessary nor appropriate for framework adaptation. A brief scan of the literature to uncover any relevant work since the publication of the CFIR was sufficient for our purposes. The literature scan in all three adaptations was limited to articles that were conceptual in nature–that is, they presented a framework or model of the intervention or addressed more broadly how context should be conceptualized and measured for that specific intervention. Our work could have easily bogged down had we included articles that included any mention of context. We also relied on the TEP to alert us to relevant literature we may have missed in the formal scan. As experts in their fields, TEP members are in the best position to know which contextual factors really matter for their research.
- **Have a TEP.** It is difficult to imagine how this adaptation could have proceeded without the input of a TEP, particularly as we were tasked with creating a tool for broad research purposes. The input of the TEP was supremely important in alerting the team to conceptual challenges and nuances that could not have been gleaned from the literature alone. Moreover, the team could not have assessed the potential utility of the frameworks without TEP involvement.
- **Include TEP members with a variety of roles and perspectives.** We recruited TEP members who represented research, practice, funding agencies, health care management, and policy (associations). The diversity of opinions created rich dialogue and likely brought to light issues that would not have been raised by a group with a more homogenous composition.
- **Have criteria for assessing framework utility and effectiveness.** The team found Gerring's criteria[2] for concept formation (i.e., familiarity, resonance, parsimony, coherence, differentiation) extremely useful in eliciting specific feedback on what TEP members liked or did not like about the framework. A systematic assessment of each construct along these criteria was out of the scope of this task and it is not clear to the team that such an exercise is even desirable given the evolving nature of the constructs in the framework.
- **Use simple graphics.** The investigative team and the TEP felt some adaptation of the CFIR graphic was warranted. Complex system interventions by their very nature do not lend themselves to simple graphics; it took multiple iterations to arrive at the final versions presented here.

- **Apply the adapted framework to a case study**. A framework or model is an abstraction, a tool for organizing and making meaning out of a complex idea or enterprise. What may look elegant and straightforward in a table can lose all sense when applied to a real-life scenario. The team used the case studies to good effect in uncovering those elements of the framework that needed additional refinement or simply did not align to current thinking.

The process of adapting the CFIR to three complex system interventions proved to be a daunting but stimulating challenge and it pushed the investigative team to think creatively about how to produce a usable product for research implementation with rigor and efficiency. Given more time and resources, the frameworks could have been vetted with a broader set of stakeholders and their content honed with more systematic methods. However, the goal of adaptation is not perfection, and care must be taken not to make a framework "endlessly complex"[1] for the sake of completeness. We encourage researchers to approach the adaptation process, and the frameworks themselves, iteratively and to document and share their experiences with colleagues. Our collective understanding of the complex phenomena we are striving to define, measure, and explain can only increase through such efforts.

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Glossary

Term	Definition
Adoption	Adoption is the intention, initial decision, or action to use the intervention. Adoption helps prepare for implementation.
Constructs	Constructs are operational definitions of theoretical concepts. Constructs may involve different meanings or measured values when applied to different practice roles.
Context	Context involves the interrelations and interactions between constructs that condition the individual and organizational use of the intervention as designed.
Domains	Domains are groupings of related constructs. Frameworks often include multiple domains.
Framework	A framework systematically identifies and organizes potential constructs and relationships to provide a conceptual tool for integrating the elements of the intervention; the environment impacting the intervention; the individuals/teams involved in the intervention; and the structures, processes, and outcomes of the intervention.
Implementation	Implementation involves deliberately initiated processes to achieve use of the intervention as designed or deliberately initiated process redesigns to guide system-wide changes of complex sociotechnical systems.
Intervention	A specific, discrete activity, action, or technique intended to achieve a desired health or health care outcome. These may be implemented singly, as combinations or bundles, or as a strategy. The later encompasses a set of practices, techniques, or interventions sharing an underlying logic or approach for achieving the desired outcome.
PCMH	"The patient-centered medical home (PCMH) is a promising primary care approach that emphasizes patient-centered, comprehensive, coordinated, accessible care, with a systematic focus on quality and safety. The goal of these models is to improve quality, cost, and patient and provider experience." [a]
Practice Roles	Practice roles include the individuals within and outside the practice, network, or organizations involved in the decision to adopt, execute, and facilitate the intervention. Examples of practice roles include external change agents, organizational leaders, and frontline staff.
Process	Process involves a course of actions (e.g., planning, engaging, and reflecting) to achieve individual- and organizational-level use of the intervention as designed.
Process Redesign	Process redesign examines interactions among components of complex sociotechnical systems (e.g., health care delivery systems) and provides resources and tools to guide system-wide changes that improve care value and its safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity of care. [b]
Transitional Care	"Transitional care is defined as a set of actions designed to ensure the coordination and continuity of health care as patients transfer between different locations or different levels of care within the same location. Representative locations include (but are not limited to) hospitals, sub-acute and post-acute nursing facilities, the patient's home, primary and specialty care offices, and long-term care facilities." [c]

Abbreviations: PCMH = Patient-Centered Medical Home.

[a]Source: Agency for Healthcare Research and Quality. (2013). Expanding the Toolbox: Methods to Study and Refine Patient-Centered Medical Home Models. *PCMH Research Methods Series*. AHRQ Publication No. 13-0012-EF.

[b]Source: Agency for Healthcare Research and Quality. (2013). *System Design: AHRQ Resources*. http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/systemdesign.html#process. Accessed June 14, 2013

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Appendix A. Detailed Results of the Literature Scans

During the title, abstract and full text reviews, we excluded articles for any of the reasons listed in Table A-1.

Table A-1. Abstract and full text exclude reasons

1. Not English language
2. No framework or theory
3. Topic is not process, redesign, PCMH nor Care Transitions
4. Does not discuss efficiency, costs, or business case elements (for CF-PR only)
5. Does not concern hospital to ambulatory care transitions for adults (for CF-CT only)
6. Published before January 2005
7. Letter to the editor
8. Other (e.g., full text not available, evaluates/applies rather than develops model, protocol or methods paper)

A general set of questions guided the abstraction of the included articles. The questions for the Care Transition abstraction were tailored to identify content not already captured in the adapted frameworks. The questions we used for abstraction were as follows:

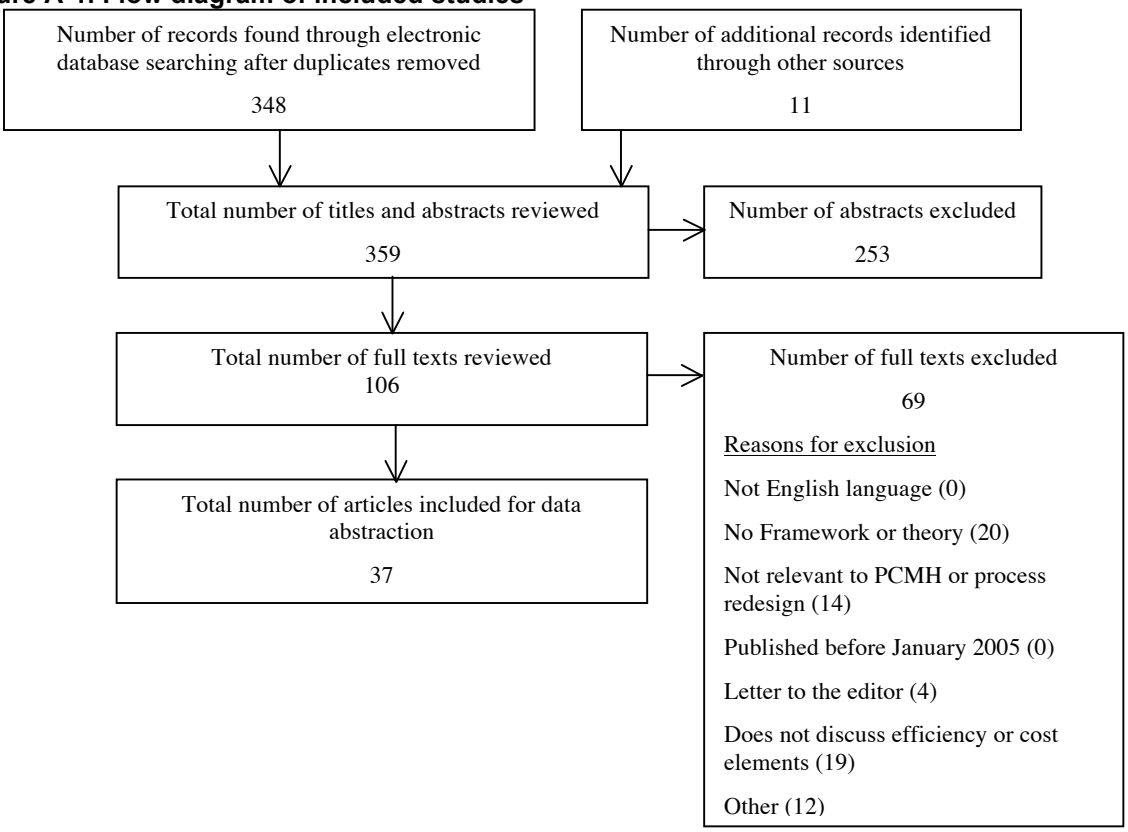
- What components (inputs, processes, outputs, outcomes) of the model are not included in the Consolidated Framework for Implementation Research (CFIR)?
- What components are unique or applicable to Patient-Centered Medical Homes (PCMH), process redesign, or Care Transitions features?
- Are the specified categories/relationships among the components different from those in the CFIR and if so, how?
- Which components or relationships should be considered for inclusion in the adapted frameworks for PCMH, process redesign, or Care Transitions?
- What components and constructs listed in the article are more applicable to models of Care Transitions from hospitals to ambulatory compared with other types of transitions? [for CF-CT only]]

Process Redesign and PCMH

Figure A-1 shows the flow diagram for included articles from the initial literature scan for the PCMH and process redesign framework adaptations. After the completion of the literature scan, the project team continued to identify and receive literature that aided in the refinement and adaptations of the frameworks throughout the multiphase process. These additional resources are cited within the report as appropriate, but are not included in the tallies for the literature scan because they did not go through the same review and data abstraction process as the articles identified by the team during the time period of the literature scan.

The main MEDLINE search yielded 226 citations and the table of contents search yielded 122 citations after removing duplicates. TEP recommendations and a search of the AHRQ Web site provided 11 more articles. After title and abstract review, we excluded 253 citations. Among the 107 full-text articles reviewed, we included 37 for data abstraction. At the full-text stage, 69 citations were excluded because they did not include a framework or theory, described activities that were not directly applicable to PCMH or process redesign, did not include cost or efficiency (if a citation pulled for process redesign), or was a letter to the editor.

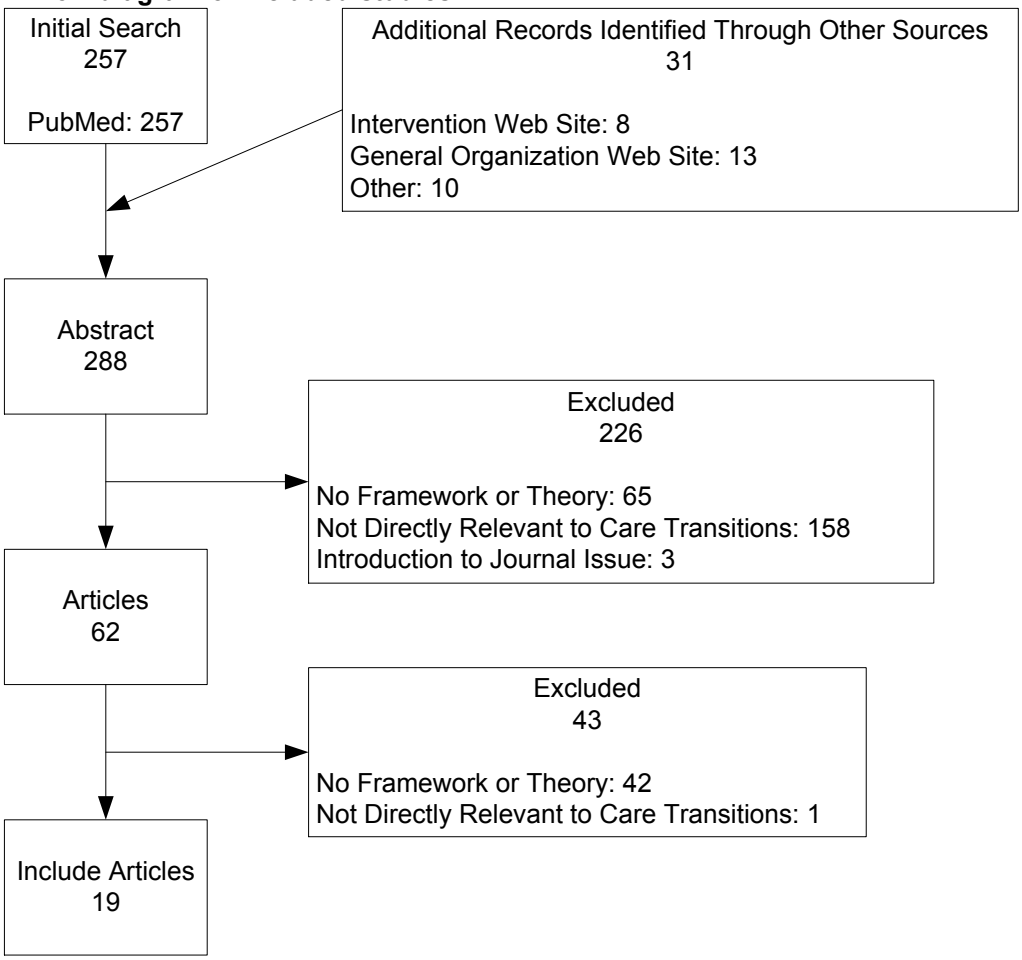
Figure A-1. Flow diagram of included studies



Care Transitions

The literature scan for Care Transitions focused on identifying contextual and theoretical frameworks related to transition interventions, specifically hospital-ambulatory transitions, and to medical illnesses. Figure A-2 shows the flow diagram for included articles. The main MEDLINE search yielded 257 citations, and the gray literature search yielded another 31 citations after removing duplicates. After title and abstract review, we excluded 226 citations. Among the 62 full-text articles reviewed, we included 19 for data abstraction. The most common reasons for exclusion were the absence of a framework or theory and a focus on activities not directly applicable to Care Transitions.

Figure A-2. Flow diagram of included studies



Appendix B. Included Articles from PCMH and Process Redesign Literature Scan

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Appendix C. TEP Composition and Methods

PCMH and Process Redesign TEP

Table C-1 shows the distribution of expertise in each TEP. The PCMH TEP included 7 members, and the process redesign TEP included 8 members (2 individuals served on both TEPs).

Table C-1. Representation on the PCMH and process redesign TEPs

PCMH TEP Member	Research and Evaluation	Management and Practice	General Implementation Research Expertise	Served on Both TEPs
1	—	—	X	X
2	X	X	—	—
3	X	—	—	—
4	X	X	—	—
5	X	X	—	—
6	—	—	X	X
7	X	—	—	—
Process Redesign TEP Member	**Research and Evaluation**	**Management and Practice**	**General Implementation Research Expertise**	**Served on Both TEPs**
1	—	—	X	X
2	X	—	—	—
3	X	—	—	—
4	X	—	—	—
5	X	—	—	—
6	—	X	—	—
7	X	—	—	—
8	—	—	X	X

Abbreviations: PCMH = Patient-Centered Medical Home; TEP = Technical Expert Panel.

To prepare the TEP for the first discussion, we sent the draft contextual frameworks a week in advance for the members to review. During the first call, a member of the team that developed the CFIR oriented the TEPs to the CFIR and answered their questions. Using the feedback from the initial discussion, we made modifications to the draft frameworks and reviewed these with the TEP on the second call. In addition, we asked the TEP to provide feedback on a set of multilevel analyses tables we created to accompany the frameworks. These tables were intended to help the user apply the constructs in the framework to multiple levels of analysis.

We used the following set of questions to elicit feedback to guide the adaptation of the CFIR:

- Is the CFIR in its original form an appropriate guide for the study of PCMH/process redesign implementation?
- What are the most important changes that need to be made to the CFIR framework?
- What are the most important constructs for PCMH/process redesign implementation research?
- Are some CFIR constructs related to *adoption vs. implementation*; are adoption constructs appropriate for an implementation framework?
- Are there entire domains or specific "variables" where we need to take into account *change* during the life course of an intervention/system change?

- Could one *level of analysis* be chosen as the focal level for a given study, with the others then seen as interacting with the focal level?
- Should *"implementation outcomes"* (Proctor et al.[6]) and *final outcomes* be included in the framework?
- Is there a manageable way of addressing the way context and the intervention interact and co-evolve?

Care Transitions TEP

Similar to the composition of TEPs for PCMH and process redesign earlier, we aimed to include individuals with diverse professional perspectives for the Care Transitions TEP encompassing research and evaluation, health care providers, and those engaged in developing and implementing Care Transitions interventions. The Care Transitions TEP included 11 members. Table C-2 shows the distribution of perspectives among the TEP.

Table C-2. Representation on the Care Transitions TEP

—	Perspective	
TEP Member	**Provider/Researcher**	**Association**
1	—	X
2	X	—
3	X	X
4	—	X
5	X	—
6	—	X
7	X	—
8	X	—
9	—	X
Co10	X	—
11	—	X

Abbreviations: TEP = Technical Expert Panel.

Using a similar protocol to the PCMH and process redesign TEPs, materials were sent to the Care Transitions TEP to review 1 week in advance of the first call. During the first call, a senior member of the investigative team gave a brief presentation on the CFIR. The orientation to the CFIR was followed by a structured discussion focused on the applicability of the draft CF-CT with the goal of addressing several overarching questions:

- Is the CFIR in its adapted form an appropriate guide for Care Transitions implementation research?
- Are the domains and constructs of the CFIR adapted appropriately for Care Transitions implementation research?
- What modifications are needed to the draft graphic (CF-CT) to provide a useful and accurate representation of Care Transitions implementation research?
- What important aspects of Care Transitions implementation research are missing from the constructs in the framework?
- How should the CF-CT frame issues of patient- or caregiver-centered care (including the key area of patient and family engagement)?
- How should links or integration between the settings for Care Transitions best be used to adapt the CFIR?

- How can the adapted CFIR best represent the concept of accountability or the home of coordination (that can rest in either or both settings)?

Based on the results of these TEP calls, we summarized input on the adaptation of the framework and developed a set of recommendations and questions for additional clarification in the second set of calls. The following questions were the focus of this second set of calls:

- Does the framework help you as a researcher identify and define the core components of the intervention?
- Does making a distinction between Inner (Core) Settings and Outer Context help you define the intervention?
- How can the framework best represent the concepts of accountability and coordination at the patient level?
- How can the framework best represent the concept of collaboration at the organizational level?
- What important aspects of Care Transitions implementation research are missing from the constructs in the framework?
- Are the domains and constructs of the framework adapted appropriately for Care Transitions implementation research?
- How should the framework frame issues of patient- or caregiver-centered care?

We also developed two case studies to evaluate the utility of the framework for designing the evaluation or a study of a typical Care Transition intervention. The subject of the first case study was the Health Improvement Collaborative of Greater Cincinnati; the second case study featured the transition of a fictional patient named "Mrs. Davis" from hospital to home. These cases were drawn from a policy brief of the Aligning Forces for Quality Initiative.[27]

Usability TEP

In a second phase of this project, the team evaluated the usability of the CF-PCMH and CF-PR by convening two new TEPs, one each to assess the PCMH and process redesign frameworks. The PCMH TEP consisted of 6 members, and the process redesign TEP had 5 members. Table C-3 shows the distribution of perspectives in each TEP.

Table C-3. Representation on the PCMH and process redesign usability TEPs

PCMH Usability TEP Member	Researcher	Health Care Executive and/or Provider
1	X	—
2	X	—
3	X	—
4	X	X
5	X	—
6	X	—
Process Redesign Usability TEP Member	**Researcher**	**Health Care Executive and/or Provider**
1	X	—
2	X	—
3	X	—
4		X
5	X	—

Abbreviations: PCMH = Patient-Centered Medical Home; TEP = Technical Expert Panel.

Each TEP met twice. During these TEP calls, members discussed the effectiveness and ease of use of the CF-PCMH and CF-PR. Effectiveness discussions focused on the following questions:

- How useful is the CF-PCMH (or CF-PR) for implementation research?
- How can the utility of the CF-PCMH (or CF-PR) be improved?

Ease of use discussions centered on the following questions:

- How can the structure and organization of the CF-PCMH (or CF-PR) be improved to enhance ease of use?
- What the pros and cons of various formats for viewing the framework (hardcopy, online, etc.) and which formats are preferred?

We followed up this TEP call with a second set of TEP calls where we provided experts with two case studies, and asked them to share their experiences while applying the CF-PCMH or CF-PR to these case studies. The PCMH TEP received two case studies of PCMH implementation initiatives: the first in a pediatric practice in Saginaw, Michigan,[30] and the second in an integrated provider network in Seattle, Washington.[31] The process redesign TEP also received two case studies: a productivity improvement activity carried out by a hospital-owned physician practice,[21] and a lean implementation in a large federally qualified health center in California.[32] The following questions guided our case study discussions.

- What contextual factors are important to this case study?
- Does the adapted CF-PCMH (or CF-PR) contain all the relevant contextual factors needed to evaluate the outcomes of interest? Are any factors missing?
- What were the challenges you encountered while applying the adapted CF-PCMH (or CF-PR) to this case study?
- Considering the contextual factors you selected for each study:
    - At what levels of analysis (e.g., individual, family, team, organization, system) should these contextual factors be measured?
    - How might these contextual factors change over time?
    - At what stage of research might these contextual factors be less or more important?
    - Should anything be added to the adapted framework that would help the researcher think through these issues?
- Did the structure and format of the adapted CF-PCMH (or CF-PR) make it easy for you to search for domains and constructs? Do you have any suggestions to improve the structure and format?
- How would you have approached the research design question if you had not been asked to use the modified CFIR? Did the addition of the modified CFIR add value to your design?

Appendix D. TEP Input on Usability

The Self Assessment and the Usability TEP conferences together provided rich information that allowed the project team to assess the processes and materials used in developing the initial CF-PR and CF-PCMH. . As we compiled the various recommendations for the frameworks, a few stood out as being repeated in various scenarios regarding both the CF-PCMH and the CF-PR (e.g., during multiple TEP calls, as a major discussion point during one TEP call, during a TEP call and through the document review). In Figure D-1, we present these recommendations. They represent solutions to some of the more frequently encountered challenges to using the framework and heavily influenced the methods for adaptation of CFIR to CT. The frameworks contained in this document are the refined versions, and already include a majority of the changes suggested below.

Figure D-1. Major recommendations to update the CF-PR and CF-PCMH

- The purpose of the frameworks and intended target group is not clear and needs to be provided.
- The various tables in the frameworks documents need modifications. The main construct table may be made clearer by reducing lengthy descriptions, streamlining the level of analysis, clarifying ambiguous terms, and adding brief examples. The multilevel analysis table and the stages of implementation table are not clear in their current form and require accompanying text to clarify their purpose.
- The graphical representation is extremely useful, and needs to be expanded and moved ahead of the framework table.
- A roadmap or how-to-use guide is necessary for new users to understand the purpose of the framework and steps to use it effectively. A case study may also be added to the framework document as part of this how-to-use guide.
- Regarding format of the frameworks, an interactive online format, with the ability to read and print from a PDF document, would be most useful because it would provide multiple modes of interaction for users. In addition, small usability-related changes to the document (such as color coding domains) can help make the framework easier to read and understand.

Abbreviations: CF-PR = Contextual Framework for Process Redesign; CF-PCMH =Contextual Framework for Patient Centered Medical Home.